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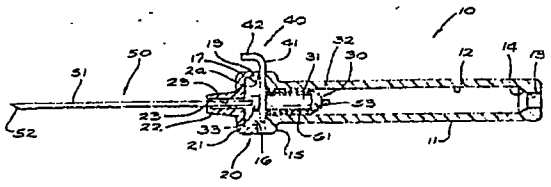
(54) Cannula insertion set with safety retracting needle.

(57) A cannula insertion needle (50) projects from the "forward" end of a hollow handle (10). After use to start a cannula, the needle is released from the end of the handle and its sharp end (52) retracted into the handle, beyond reach. Preferably the handle has an aperture (23) big enough for the needle but too small for fingertips. In one preferred form of the invention, the needle rides in a carrier block (30) that slides inside the handle. Initially the block is secured in the handle against the forward end, with the sharp end of the needle protruding outward through the aperture. A manually releasable latch (40) holds the block in this position. The latch mechanism includes mutually interfering stop elements on the exterior of the block and interior of the handle. After the cannula is in place, the person using the device withdraws the needle from the patient and manually triggers the carrier-block latch (42) by squeezing or rotating one of the stop elements out of engagement with the other. Then a coiled spring (61) drives the block rearward to retract the needle into the handle. At the rear end of the handle a stop (13) halts the carrier block and needle so that they are safely confined within the handle. A standard size tube fitting on the rear of the handle and a hollow needle permit liquid flow to or from the patient through the handle temporarily.

FIG. 1



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CANNULA INSERTION SET WITH SAFETY RETRACTING NEEDLE

1. FIELD OF THE INVENTION

This invention relates generally to medical appliances; and more particularly to a device for inserting a cannula --such as an intravenous cannula --into a patient's body.

2. PRIOR ART

As is well known, there are myriad very important medical uses for intravenous and intraarterial tubes and other indwelling catheters. It is also known in the medical community that a severe problem has developed in relation to all such devices.

That problem arises from the continuing presence of horrible diseases, particularly fatal and currently incurable diseases such as acquired immune deficiency syndrome ("AIDS") and hepatitis, transmitted by exchange of body substances between people. These diseases have led medical institutions to exclusively use disposable needles for injections and for catheter or cannula implants.

A severe residual risk remains, however, for medical personnel themselves in the inadvertent touching of needle tips after withdrawal from infected patients. Medical needles are designed and manufactured specifically to be extremely sharp and to puncture skin and flesh with only the slightest pressure.

As a result, what would ordinarily be an inconsequential scratch or pinprick can bring and has brought severe disease or even death to many medical staff members and others. Needless to say, health-care professionals are well aware of this risk and take considerable precautions to avoid such inadvertent punctures; thus the risk is reduced on a "probability" basis to an exceedingly small value.

Nevertheless, the exposure is so massive for working doctors, nurses and technicians that occasional punctures are inevitable. As a practical matter, it is virtually impossible for such an individual to reduce the incidence of accidental puncture to less than, say, one every year or perhaps one every few years.

Of course, not every such puncture follows contamination of the needle by a patient carrying a transmissible fatal disease. Nevertheless, there are enough medical personnel and enough such patients that a significant number of medical staffers die --and of course a greater number become very sick --from these accidents.

In discussion of this problem, needles of the types used with syringes commonly come to prominence. Though the word "hypodermic" has somewhat passed out of current usage in the medical profession, I shall for purposes of definiteness and simplicity refer to needles used with syringes for giving injections as "hypodermic needles." Needles used in drawing blood will be called "phlebotomy needles." By this terminology I mean to clearly distinguish all such needles from needles that are used for cannula insertion, the field of the present invention.

Hypodermic and phlebotomy needles are prominent in discussion because they are used to conspicuously and in such enormous quantity. Interestingly, however, the actual manual manipulations involved in using hypodermic and phlebotomy needles are relatively favorable to avoiding puncture accidents.

More specifically: after a hypodermic needle is withdrawn from a patient, the person using the needle in some circumstances (e. g., intramuscular injections) immediately has both hands available to properly deal with the needle. In normal circumstances he or she can promptly sheath and discard it before further tending to the patient.

In many other situations (e. g., intravenous injection) the person using the hypodermic needle almost always has one hand free to at least hold the needle until it can be properly sheathed. In some situations that are more demanding of dexterity (e. g., blood withdrawal), the person using the phlebotomy needle usually can at least find a second to place it temporarily well out of the way until there is time for safe disposal.

(It will be understood that my discussion here is directed to the relatively lower danger in procedures for injections or blood withdrawal, as contrasted with the procedures for cannula insertion. Thus I do not mean to imply that once properly sheathed, hypodermic needles used for intramuscular injections are necessarily safe: there of course remains a certain amount of potential for inadvertent unsheathing and many other kinds of accidents.)

Of course there are exceptions to the foregoing general proposition that injection and phlebotomy procedures are relatively less dangerous than cannula-insertion procedures. There are learning situations and emergencies, and circumstances in which the usual manipulations are complicated by patient mental or physical condition. These are, however, probably only between ten and twenty

percent of all instances of use of hypodermic and phlebotomy needles.

Procedures for insertion of intravenous or other cannulae are not so favorable for avoidance of accidental punctures. When a cannula has been emplaced in a patient's blood vessel, for example, the cannula potentially forms an open channel for conveyance of the patient's blood to the outside of the body.

The patient's blood vessel must therefore be blocked firmly until and while this channel is connected to a mating tube --which is pressurized, typically with fluid to be infused into the patient's body. In practice the doctor, nurse or technician usually blocks the blood vessel by pressing manually on the outside of the patient's body, just at the tip of the cannula.

This pressure is maintained continuously until the tube is attached to the cannula. From this it will be understood that, before the medical staff member will have both hands free, there will be an intermediate time during which neither hand is free.

In some instances the needle used to emplace the cannula is hollow, and the tubing can be temporarily connected to the back of that needle. This is in fact only temporary relief, however, since eventually the tubing must be removed from the needle, the needle removed from the patient, and the tube reconnected to the cannula.

In some cases the person using the needle is able to place nearby, in advance, a tray in which to temporarily deposit the unsheathed needle without moving out of arm's reach of the patient. This option is not always available, however, and in any event using such a tray is itself a risky proposition.

As a result, a medical staff member who frequently start intravenous tubes and the like typically becomes adept at sheathing needles with one hand. Heretofore this has been the least problematical solution to a continuing problem.

It is nevertheless a very poor solution. It is precisely the kind of maneuver that sooner or later goes astray, leading to an occasional scratch or puncture and thereby statistically to severe illness or death.

Fig. 16 shows a device generally representative of present-day standard, commercially available cannula insertion kits. The familiar term in the health-care professions for such a prior-art device is "I. V. insertion set" --the initials standing for the word "intravenous."

The needle is stainless steel and extremely sharp at its frontal end, which is the left end as drawn in Fig. 16. The shank of the needle is permanently secured into the front end of a molded plastic cylinder, with the sharp end of the needle projecting forward out from the cylinder as illustrated. The cylinder may be typically made of polycarbonate.

For reasons that will shortly appear, the needle is preferably but not necessarily hollow. I am not familiar with the manufacturing details of these articles, but it would appear that the needle may be secured to the cylinder by a press fit or shrink fit, or by molding the plastic cylinder in place on the needle.

A separate catheter assembly or "cannula" fits very snugly, but removably, onto the forwardly projecting part of the needle. The tapered front of the cannula slides with the needle through a patient's skin and flesh.

The rear portion or hub of the cannula is radially enlarged and formed to define a very slightly tapered rearward receptacle for a standard-diameter tube, such as intravenous supply tubing. The cannula, or at least its part that is fitted snugly onto the shank of the needle, is of a biologically inert but very slippery material, such as that available commercially under the well known trade name "Teflon." The hub is typically of high-molecular-weight polypropylene or the like.

In use the needle and cannula are inserted together into a patient's blood vessel --or in some cases into a body cavity, or an abscess, or wherever fluid communication is to be established. As previously mentioned, the medical staff person using the device then usually applies pressure to the outside of the patient's body just ahead of the needle tip, to prevent outward flow of blood.

The medical staff member then withdraws the needle, leaving the cannula in place within the body. Finally the fluid communication is completed by insertion of a standard-diameter tube into the receptacle at the rear end of the cannula.

In a typical cannula insertion set the rearward portion of the cylinder is formed very similarly to the rear end of the cannula, making allowance for the difference in properties of the cylinder and cannula materials. This shaping permits attachment of the standard tubing to the cylinder rather than the cannula.

In use, when it is not necessary or desirable to leave the cannula along in the patient's body with the tubulation attached --or if it is not desirable to do so immediately --an intravenous or like connection can be made through the steel needle. It is for this reason that the needle is advantageously hollow.

A separate safety cover (not illustrated) is typically supplied in place on each insertion set. The separate safety cover firmly grips the cylinder and entirely covers the needle, to prevent accidental puncture and to prevent accidental contamination of the needle by substances in the environment, before use.

To use the insertion set, the safety cover must

be entirely removed and set aside.

As already outlined, our focus of concern now shifts to the possibility that the needle may be contaminated by substances in the patient, during use. Accordingly the safety cover is to be replaced over the sharp end of the needle to prevent accidental puncture and, particularly, to prevent contact of people other than the patient, with possible contaminants on the needle.

It is here that the prior art fails to be effective, since the process of replacing the safety cover is subject to the risks previously described. As far as I know, the medical marketplace lacks any appliance or apparatus aimed at solving this problem.

The closest safety device that may be at all relevant is actually in a different field, namely the field of hypodermic needles. That device is a special form of hypodermic needle, available commercially from the firm ICU Medical, Inc. under the trade name "ICU High Risk Needle."

The ICU device is fitted with a sliding sheath that is carried on the shaft of the hypodermic needle itself. After use the sheath is advanced forward over the needle tip.

This device undoubtedly serves a useful purpose, and it is certainly not my desire to criticize what is apparently the only commercial effort directed to problems even remotely analogous to those of interest here. On the other hand, that device evidently has limitations that should be mentioned.

First, the ICU High Risk Needle is offered as a special item at a special price, for use only with patients known to be "high risk" patients. Not all patients carrying transmissible fatal diseases are known to be high risks.

Secondly, the sheath is attached halfway out the needle, where there would appear to be potential for inadvertent application of lateral force with sufficient leverage to snap off the needle. If that should occur before the sheath were fully advanced, the potential for accidental puncture could be substantial.

Thirdly, it is not clear from commercial literature on the product that the sheath locks in place when advanced --or, if so, that it locks firmly enough to withstand normal jarring in the workplace. Without such a feature, the device would seem to offer very limited protection.

Finally, as already suggested, the ICU product is neither designed nor offered for use in insertion of cannulae or the like. It appears to require substantial modification for any such use.

A number of patents have been issued for devices that shield medical needles, but they are virtually all for hypodermic or phlebotomy needles. Only one of these patents even mentions needles used in emplacing intravenous cannulae. That is United States Patent 4,592,774, issued June 3, 1986, to Janine C. Jagger et al. The introductory passages of the Jagger patent refers to, e. g. --

safety venipuncture devices having needle retracting means, particularly hypodermic needles having a retractable needle, vacuum tube phlebotomy systems having retractable needles, and intravenous devices having retractable needles.

Once past the introductory portions of the patent, however, Jagger et al. confine their disclosure to hypodermic and phlebotomal uses. They never again mention any possibility of applying their invention to intravenous devices.

In other words, although the Jagger patent represents that it encompasses disclosures within the field of the present invention, that does not appear to be so. The Jagger disclosure fails to include any specific disclosure directed to safety inserting a cannula into a patient.

Jagger et al. do illustrate and describe a device that facilitates retraction of a hypodermic needle into a personnel-protective enclosure. They also show and describe another device that similarly facilitates retraction of a phlebotomy needle into a like enclosure. In both of these devices the retraction procedure is relatively cumbersome.

In the hypodermic device, the needle is mounted by a relatively tight press fit to the forward end of a syringe that is fitted within the handle. The needle also extends in a relatively loose press fit through a hole in the front of the handle.

After use, the syringe must be pulled bodily out of the back end of the handle, carrying the needle rearward out of its front-end press fit with the handle, and into the cavity within the handle. The needle is carried in a flange that is too wide to escape from the rear end of the handle, and accordingly is pulled away from its tight press fit to the front end of the syringe. It is thus trapped within the handle.

In the phlebotomy device, the blood-collection receptacle is initially enclosed within an outer housing/handle during use. The rear end of the needle passes in a tight friction fit through an elastomeric stopper on the receptacle.

Thereafter the receptacle is used as a tool to unscrew the needle from the forward end of the handle. Then the receptacle stopper is pulled off the rear end of the needle, so that the receptacle with its blood sample can be removed from the handle. As the receptacle is withdrawn, the needle is trapped by its flange in the handle.

Thus the two forms of the Jagger invention that are described require the user to actually pull the needle all the way back through the hole in the handle. This motion must be continued until the needle is entirely within the handle cavity.

It will be seen immediately that for a needle

more than about an inch long this manipulation is difficult to accomplish using only one hand. The difficulty will be compounded if the maneuver must be performed with only part of the user's attention, as is often the case.

In most instances the necessary manual operations must include several motions in sequence. What is required is a compound motion, each stage of which is typically of relatively large amplitude in comparison with the length of the needle and the size of the user's hand.

As a matter of ergonomics, the requirement for such large-amplitude and compound motions is inherently adverse to definite, reliable and therefore safe retraction. This is particularly so for medical personnel under harried circumstances.

Other factors, specific to the hypodermic and phlebotomy applications of the Jagger invention, make the procedure even more awkward and difficult. First, as to the Jagger hypodermic needle, proper retraction depends upon maintenance of the design relationships between two friction levels. These relations are too easily upset.

For example, they can be disturbed by temperature variations in storage, beyond the knowledge of the person using the device. They can also be disturbed by leakage of congealable or sticky substances such as blood or sucrose solution, through the large opening at the rear of the handle and into the exposed seams between the handle and the needle flange.

The necessary friction relationships can also be disturbed by imperfect insertion of the syringe tip into its mating receptacle at the rear of the needle flange. That procedure, which in many cases is performed by medical technicians on site, rather than the manufacturer's personnel, can at least in principle damage either of the friction-fitting surfaces involved.

In such circumstances the syringe can be extracted from the needle flange before the needle is retracted --leaving no proper means for retraction.

As to the Jagger phlebotomy needle, the arrangement for retraction is even more adverse to reliable operation. The flange of the phlebotomy needle must actually be unscrewed before it can be pulled back into the handle.

In any event, it is not suggested how the Jagger invention might be configured or might function for use in a cannula insertion device. As previously mentioned, that is the field of the present invention.

Other prior patents describe devices for automatic or semiautomatic resheathing of hypodermic syringes. These, however, do not even mention the possibility of intravenous-cannula use.

United States Patent 4,026,287 to Haller is among the better of these, since it at least provides for retraction of the used needle into a cavity in a unitary, sturdy structure. The Haller device, however, requires screwing the syringe plunger into the back of the needle flange after use, to destroy a frangible seal around the flange and then retract the needle.

Haller also fails to protect against inadvertent insertion of fingertips into the syringe barrel. Even more serious is the fact that Haller's syringe plunger can remain in place, held only by detents at the rear of the barrel.

The Haller plunger thus remains dangerously ready to drive the needle forward again if the syringe is accidentally jarred past the detents. In addition, Haller's device and most of the others discussed below are disadvantageous in that their after-use sheathing configurations are at least as long as --or in some cases longer than --the initial or before-use configurations.

A device to be discarded, particularly one that is dangerous if broken open, should not be so extended and should not have a multiple-stage structure. Such configurations invite breakage and potentially serious accident.

(It should be noted in passing that in the present context the title of Haller's patent may be somewhat misleading. That title is "Syringe with Retractable Cannula" --her term "cannula," however, does not refer to an indwelling-catheter cannula, but simply to the forward end of the syringe body.)

United States Patent 4,631,057 to Mitchell also leaves the needle accessible to finger tips through the unsealed forward end of the sheath. Mitchell's device also shares with the Haller device an undesirable sensitivity to jarring the device out of its safety detents, and in addition a similar undesirable extended after-use configuration.

Other patented devices with a like vulnerability to jarring out of detents and a like extended postuse configuration, but at least providing better frontal shielding against fingertip insertion, are United States Patents 4,573,976 (Sampson), 4,643,199 (Jennings, Jr. et al.) and 4,643,200 (Jennings, Jr.).

Worthy of mention for its provision of more positive resistance to jarring of the needle out of retracted position is United States Patent 4,425,120 to Sampson et al. That device pays for its better safety locking with complexity of the manual manipulations required in use.

Similar observations apply to United States Patent 3,890,971 to Leeson, which offers a relatively very compact and stable postuse configuration, but at the cost of a relatively complicated mechanism and large-amplitude motions to effect the resheathing.

Numerous devices for providing merely visual shielding or screening of hypodermic syringes have also been patented. Among these are United

States Patents 2,876,770 (White), 2,674,246 (Bower) and 3,134,380 (Armao). Such devices are actually counterproductive with respect to present purposes, since they effectively cancel the presence of a dangerously sharp and possibly contaminated needle.

Thus the prior art has failed to provide a suitable safety device for use under modern conditions in the field of the present invention --medical indwelling-cannula insertion. No prior-art device adequately protects people from contact with portions of the device that have been within the patient. In particular, no prior-art device provides the necessary sure and easy operation that is essential to the effectiveness of such protection.

SUMMARY OF THE DISCLOSURE

My invention is a safety device for use in inserting a cannula into a patient. It also serves thereafter to protect medical personnel, trash-handling personnel, and any other people who may have casual contact with the device after its use. The device protects all such individuals from contact with portions of the device that have been within the patient.

The device of my invention includes a needle for piercing the patient, and for guiding and carrying a cannula into place within the patient. The needle has a shaft with at least one sharp end.

My invention also has a hollow handle that is adapted to enclose at least the sharp end of the needle. The handle is particularly adapted to so enclose the sharp end beyond reach of such people's fingers.

In addition the invention includes some means for securing the shaft of the needle to the handle, with the sharp end projecting from the handle. For purposes of generality in description, I shall refer to these means as the "securing means."

My invention further includes some means for releasing the securing means --and for retracting the sharp end of the needle into the handle. These means I shall, again for generality, call the "releasing and retracting means." Retraction of the needle by these means is substantially permanent.

The releasing and retracting means of my invention are manually actuable by a simple unitary motion. By "simple unitary" motion I mean a motion that is not compound, one that entails a single-stage stroke or movement in just one direction.

The amplitude of this motion is substantially shorter than the length of the needle. Alternatively, it may be described as small compared with the size of the user's fingers, or hand generally.

The foregoing may be a description of my invention in its most general form. As will be appreciated, however, there are additional features which I prefer to incorporate in my invention to particularly optimize its efficacy.

Such desirable and preferred features include an aperture, defined in the handle, that is small compared with the fingers of such people to be protected --but large enough for passage of the needle. Another preferred feature is a trigger mechanism, forming part of the releasing and retracting means, that is operable from outside the handle.

The releasing and retracting means also preferably include some means --such as, for example, a coil spring --for positively biasing the sharp end of the needle toward retraction into the handle. After retraction has actually occurred, these biasing means preferably continue to operate, to retain the sharp end of the needle retracted within the handle.

My invention preferably includes a block that is fixed to and extending from the needle, and that forms a part of the securing means. The block is adapted to be restrained within the handle, with the sharp end of the needle projecting from the handle.

The block, when present, is also responsive to the releasing and retracting means, to withdraw the needle into the handle. The releasing and retracting means are preferably actuable by just one hand of a user of the device. It is also strongly preferable that a user can actuate these means without looking at the device during the actuation.

More specifically, I prefer to provide stop elements respectively defined within the handle and on the block. These elements engage each other to restrain the block from retracting the needle.

I also prefer to provide a trigger mechanism, including a manually operable release member. The trigger mechanism disengages the stop elements from one another to release the block and thereby retract the needle.

As previously mentioned, my device is for use with a cannula. The cannula fits over the needle and is guided by it into the patient's body.

Thus the cannula may be regarded as a part of the environment of my invention. For some purposes, however, to the extent indicated in the appended claims, it is appropriate to regard the cannula as a part of the invention itself.

All of the foregoing operational principles and advantages of the present invention will be more fully appreciated upon consideration of the following detailed description, with reference to the appended drawings, of which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevation, mostly in longitudinal section, of a preferred embodiment of my invention, shown with the needle secured in extended position for starting a cannula.

Fig. 2 is an enlarged and exploded perspective drawing, drawn interrupted at one end, of some of the parts of the Fig. 1 embodiment.

Fig. 3 is a similar view of a variant form of some of the Fig. 2 parts.

Fig. 3a is a somewhat schematic end elevation of the Fig. 3 parts assembled.

Fig. 4 is a side elevation, mostly in longitudinal section, of a second embodiment of my invention, showing the needle in extended position for use in starting a cannula.

Fig. 5 is a similar view of the Fig. 4 embodiment, showing the device a fraction of a second after the release mechanism is actuated, with the needle moved very slightly back from its Fig. 4 position toward its retracted position.

Fig. 6 is a similar view of the Fig. 4 embodiment, showing the needle fully retracted.

Fig. 7 is a similar view of a third embodiment of my invention, showing the needle in extended position for use in starting a cannula.

Fig. 8 is a similar view of the Fig. 7 embodiment, showing the needle fully retracted.

Fig. 9 is a somewhat schematic enlarged side elevation, mostly in longitudinal section and drawn interrupted in two areas, of a fourth embodiment of my invention.

Fig. 10 is a somewhat schematic enlarged elevational cross-section of the same embodiment, taken along the line 10-10 in Fig. 9.

Fig. 11 is a schematic enlarged side elevation, mostly in longitudinal section and drawn interrupted in two areas, of a conceptually generalized form of a certain group of embodiments of my invention, showing the needle in extended position for use in starting a cannula. It is to be very clearly understood that many other embodiments of my invention, some but not all of which are illustrated and discussed in this document, are outside the group of embodiments that is represented in generalized form by Fig. 11.

This same understanding applies equally to Fig. 12, which is a schematic perspective of the Fig. 11 generalized form of a certain group of embodiments.

Fig. 13 is a highly schematic enlarged perspective view of a fifth embodiment of my invention.

Figs. 13a and 13b are like schematic side and end elevations, respectively, of the Fig 13 embodiment.

Fig. 14 is a somewhat schematic enlarged side elevation, mostly in longitudinal section and drawn interrupted in two areas, of a fifth embodiment of my invention --with the needle in extended position for use in starting a cannula.

Fig. 15 is a somewhat schematic enlarged elevation of the same embodiment in cross-section, taken along the line 15-15 in Fig. 14 --but with the needle extracted.

Fig. 16 is a somewhat schematic enlarged elevation, in longitudinal section, representative of the prior art.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in Figs. 1 and 2, an embodiment of my invention which I now prefer includes a shaped hollow handle 10. This embodiment also includes a nosepiece 20 that is securely fixed to a forward end of the handle 10, and a carrier block 30 that is slidably disposed within the handle 10.

The embodiment of Figs. 1 and 2 also includes a latch 40 that secures the carrier block 30 near the forward end of the handle, close to the nosepiece 20; and a needle 50 that is carried by the block 30 and extends from the handle 10 through the nosepiece 20. Finally, this embodiment includes a spring 60 that is positioned within the handle 10 and encircles part of the carrier block.

The various parts of this embodiment of my invention are particularly configured for ease and economy in manufacture. Accordingly in the description of this embodiment I shall mention many details of configuration. I mean it to be understood that all such details are included to enable a person skilled in the art to practice my invention in its best mode as currently envisioned, and in particular very cost-effectively.

The handle 10 is preferably but not necessarily injection molded from plastic such as polycarbonate. It includes a long, generally right-circularly cylindrical outer grip surface 11, radially enlarged near its forward end to form a thumb stop 15.

The thumb stop, in turn, is the rearward part of a latch-housing portion 15-19 --better seen in Fig. 2. The thumb stop 15 is a right-circular cylinder, much shorter than but conaxial with the outer grip surface 11.

The remainder of the latch-housing portion 15-19 is also circularly symmetrical, except that it is bisected at its forward end by a broad transverse latch-guide slot 16, 18. The transverse latch-guide slot 16, 18 has a bottom surface 18 and two opposed side walls 16.

As viewed from the end of the device, each

side wall 16 of the latch-guide slot 16, 18 is formed along a chord of the circular shape of the thumb stop 15. Thus in effect the latch-guide slot 16, 18 divides the forward portion of the latch housing 15-19 into two identical upstanding pillars as seen clearly in Fig. 2. Each pillar is formed as a segment on the chord.

A circumferential groove 19, also better seen in Fig. 2, is formed near the forward end of the latch housing 15-19. This groove 19 is spaced away from the bottom surface 18 of the latch-guide slot 16, 18. At the very end of the latch housing there is a flange 17, of diameter smaller than that of the thumb stop 15.

I prefer to form neither the groove 19 nor the flange 17 as rectangular in longitudinal section. Rather, to facilitate removal from an injection mold --and also to ease snap-together assembly with the nosepiece 20 --I prefer to form the groove 19 and the flange 17 as arcs in longitudinal section.

A centered longitudinal bore 12 is formed within the handle 10, exposed at the bottom surface 18 of the latch-guide slot 16, 18. This bore is very generally right-circularly cylindrical, but preferably has a very slight taper or draft widening toward the rear end of the handle to facilitate removal of the handle from a mold.

Near the rear end of the bore 12, however, there is formed an internally frustoconical stop surface 14 --narrowing the bore 12 slightly. At the extreme end of the bore 12 is a short end section 13, opening at the rear end of the handle 10.

The end section 13 of the bore is preferably slightly tapered outward toward the rear, and (notwithstanding the drawing) of the same length and taper as the needle guide 22. The taper of the frustoconical stop surface 14 is slight, and the overall diametral inset from the long section 12 of the bore to the end section 13 of the bore is very slight.

By virtue of these details of configuration, the handle can be popped out of an injection or other mold by means of a slight deformation (expansion) of the rear end. That is, a separate core piece in the mold is not needed.

The nosepiece 20 is a right-circularly symmetrical article with two main sections: a relatively slender forward needle guide 22 and a radially enlarged rearward canopy 21. The needle guide 22 has a central bore that is somewhat larger than the diameter of the needle 50.

At the extreme tip of the needle guide 22 this central bore narrows to a fine aperture 23. The diameter of the end aperture 23 is chosen as a tradeoff between (1) complete stabilization of the needle and (2) minimum friction in sliding clearance between the guide 22 and needle.

The canopy 21 has a right-circularly cylindrical outer surface, preferably matching the outer surface of the thumb stop 15. Formed in the rear end of the canopy is a cavity, internally shaped to mate securely with the contours of the latch housing 15-19.

More particularly, at the very end of the cavity there is an inward flange or lip 24 (Fig. 1) that accurately fits into and engages the groove 19 of the latch housing 15-19. Due to the previously mentioned spacing of the groove 19 away from the bottom surface 18 of the latch-guide slot 16, 18, the inward lip 24 of the nosepiece 20 is similarly spaced from the bottom surface 18. The resulting gap defines a track for operation of the latch 40.

The nosepiece can be made of the plastic available commercially under the trade name "Delrin." That material is selected primarily because it is easy to form.

The carrier block 30 has a very narrow central bore in which the needle 50 is tightly gripped. The block 30, also of Delrin, may be press-fit, shrink-fit, and/or cemented on the needle, or molded in place.

The outside of the carrier block 30 is circularly symmetrical. It has an extended barrel 31 that may be right-circularly cylindrical. At the rear end of the barrel 31 is a frustoconical stop section 32 whose forward end is radially enlarged relative to the barrel 31. The stop section tapers inward toward the extreme rear of the block 30.

The rear, frustoconical surface of the stop section 32 is shaped to seat against the previously mentioned internal frustoconical stop section 13 of the handle 10, when the needle is fully retracted. The front end of the stop section 32 forms a generally planar, annular, step radially outward from the barrel 31, for purposes to be seen shortly.

The forward end section 33 of the block 30 is of the same diameter as the barrel section 31. Between the forward end section 33 and the barrel 31, however, there is formed a circumferential latch groove. Thus the forward end section 33 forms a flange adjacent to and just forward from the latch groove.

The latch 40 has a flat side section 41, and at one end of the slide a short pushbutton section 42 bent or formed at right angles to the slide 41. A keyhole-shaped cutout 43, 44, is defined in the slide.

The enlarged portion 43 of this cutout is nearer to the pushbutton 42. The end 45 of the slide 41 opposite the pushbutton 42 lies immediately past the narrowed portion 44 of the cutout 43, 44. The latch can be made from a suitably selected 300 series stainless steel.

The needle 50, with its shaft 51, sharpened tip 52, and rear end 53, is generally conventional --and also of stainless steel. It is no longer than usual, to

allow for the extra length required to pass into and through the carrier block 30. The block 30 is fixed upon the needle shaft 51 very near the rear end 53 of the needle.

Finally the preferred embodiment of Figs. 1 and 2 includes a coil spring 61, sized to encircle the outside diameter of the carrier-block barrel 31. The spring should be long enough to hold the mechanism fully retracted. The minimum diameter of the handle bore 12 is selected to just enclose the spring 61 --without significantly restricting the free expansion of the spring.

To assemble the device, the carrier block 30 is first fixed to the needle 50 as previously described. Then the needle 50 is inserted through the spring 61, until the carrier block 30 reaches the spring. This same general motion is then continued, to insert the flange 33 and barrel 31 of the carrier block through the spring 61.

The result of this procedure is that one end of the spring is seated against the previously mentioned stop at the rear end of the carrier-block barrel 31.

Next the needle is inserted into the keyhole cutout 43, 44 in the slide 41, until the carrier block 30 reaches the slide 41. The same general motion is continued, passing the flange 33 at the forward end of the carrier block through the enlarged section 43 of the keyhole cutout 43, 44 in the slide 41.

The result of this procedure is to align the slide 41 longitudinally with the circumferential groove (between the barrel 31 and flange 33) in the carrier block 30. Next the slide 41 is moved laterally toward the pushbutton 42 so that the narrower portion 44 of the keyhole cutout 43, 44 is captured in the circumferential groove in the block 30.

The carrier block 30, with the needle 50, spring 60 and latch 40 in effect threaded upon it as just described, is then inserted rear-end-first into the front end of the bore 12 in the handle 10.

The slide 41 thus fits between the two side walls 16 of the latch-guide slot 16, 18, and rests against the bottom surface 18 of the slot. The needle is then inserted through the bore 29 and clearance aperture 23 in the nosepiece 20; and the shaped forward end 16, 17, 19 of the latch guide is then snapped in place within the canopy 21 of the nosepiece 20.

The handle 10 is now in effect longer, by the added length of the nosepiece 20. When assembled in this way, the slide portion 41 of the latch 40 is positioned in the previously mentioned "track" that is defined between the bottom surface 18 (Fig. 2) of the latch-guide slot 16, 18 and the inner lip 19 (Fig. 1) of the nosepiece 22.

The pushbutton 42 is pulled fully outward radially from the latch-guide housing 15-19 (or, to now put it more completely, 15-21). The needle 50 is now firmly secured in position, extending forward from the effectively lengthened handle.

After the nosepiece 20 is snapped into place on the end of the handle 10, these two parts are preferably secured together as by sonic welding. (If preferred they can be held together by cement, naturally applied before assembly, or by through pins, etc.) This procedure is desirable to ensure permanence of attachment --and thus permanence of capture of the needle after retraction.

My invention makes use of a cannula generally similar to the conventional one shown in Fig. 16. Since, as can be seen, the safety insertion set of my invention is slightly longer than some prior-art insertion sets, I prefer to shorten the cannula hub slightly to minimize the overall length of my invention.

Depending upon the precise shaping of the forward portions of my invention, cannulae for use with my invention thus may be entirely conventional, or advantageously may be adapted by shortening of the hub.

For simplicity and clarity of the drawings of my invention, I have omitted the cannula from them. All of Figs. 1 through 12, however, are to be taken as incorporating the cannula in its positioning over the needle shank, by reference to Fig. 16.

The rearmost bore 13 of the handle 10 should preferably be given the same diameter as the internal diameter of the cannula hub. It should also be given the same overall length, though Fig. 1 does not so illustrate it. Thus the prior-art feature of temporary fluid connectability through the hollow needle 50 can be preserved in my apparatus.

In addition, a very generally conventional safety cover for the needle of my invention should also be provided, to protect against accidental puncture and against contamination of the needle before use. The cover must be adapted to fit over the pushbutton 42 without triggering it --and preferably also to fit between the pushbutton 42 and the canopy 21, to deter movement of the slide 41 due to vibration in shipment or other handling.

After use, however, the safety cover may be thrown away. In particular, it may be discarded either together with my invention or separately, since the needle is automatically sheathed without that cover.

Dimensions of the nosepiece needle guide 22 and rear bore 13 of my preferred embodiment should be the same as the dimensions of standard cannulae, to mate with standard tubing. Both should be roughly 0.275 inch long, and taper from 0.15 inch at the front to 0.20 inch at the rear.

Other dimensions of my preferred embodiment of Figs. 1 are roughly (in inches):

3.5 length from rear end of handle to forward surface of canopy

2.3 length from forward surface of canopy to tip of needle

0.500 outside diameter of nosepiece canopy

0.350 outside diameter of handle grip surface

0.165 inside diameter of handle bore near trigger

0.170 inside diameter of handle bore near rear end

0.625 length of carrier block

0.165 outside diameter of carrier-block stop section

0.120 outside diameter of carrier block barrel.

Although I consider the embodiment described above highly desirable, various features could in principle be omitted and the device still correspond to my invention as most broadly envisioned. For example, a tension spring (rather than a compression spring as shown) could be secured to a small hole or hook near the rear end of the needle, to pull the needle into a closed handle without the intermediary of a carrier block.

Alternatively the spring could be omitted, and the needle arranged to fall into the handle under the influence of gravity when a latch is released. Furthermore, it is not strictly necessary that the needle be hollow: that is only important if it is desired to maintain the user's option to make temporary fluid connection through the needle.

Moreover it is not necessary that the rear end of the needle initially be within the handle. Some other element of the apparatus could instead pull the rear end of the needle into the handle when a latch is released.

On the other hand, it is not necesssary that after actuation of the latch the rear end of the needle come to rest within the handle: in principle the "back" of the needle could protrude from the rear end of the handle. In this case proper provision must be made, however, to prevent the needle from being accidentally reextended forward through the nosepiece.

Most or all of these variations, as will be seen, are applicable to other embodiments of my invention that are shown in Figs. 3 through 15 and discussed below. For positive, maximally safe operation, I personally prefer not to employ any of the variations described in the preceding four paragraphs. Nevertheless some or all of them could possibly or probably be made safe and convenient by careful design, and they are accordingly within the scope of certain of my appended claims.

I have had a working model of the Fig. 1 and 2 embodiment constructed, and I have found its operation excellent. That embodiment, however, may be subject to improvement.

For example, I believe that the variant that is illustrated in Figs. 3 and 3a may be preferable, though I have not constructed a working model for direct comparison. In Figs. 3 and 3a the pushbutton is a formed annular-segment plastic piece 142, with an antislip peripheral surface 146; and the nosepiece has a section 126, 127 cut out to accommodate the pushbutton 146.

This configuration seems probably preferably, for ease of operation. The fingers of a person using the device will normally be kept behind the thumb stop 15 (Figs. 1 and 2), and therefore are unlikely to accidentally operate the button 146.

Even in event of such an accident, there is no harm to the patient or medical personnel. The main adverse result is economic: another insertion set must be obtained. Regular users of the device will quickly learn to avoid inadvertent triggering of the latch.

Another refinement shown in Fig. 3 is that ratchet-shaped detents 147 are provided on the edges of the slide, to interact with corresponding features (not illustrated) formed in the slide walls 16 of the guide slot 16, 18. These detents 147 will prevent the trigger from being rest, and thereby discourage attempts to reuse the needle.

I shall now mention still another desirable characteristic of my preferred embodiment, perhaps not clearly illustrated. I prefer to slightly increase the diameter of the large end of the frustoconical stop section 32 of the carrier block so that it provides a fluid seal against the inside bore 12 of the handle 10 --when the trigger is not actuated.

This arrangement facilitates effective fluid communication through the hollow needle by minimizing reliance on maintenance of sanitation at the many intricate surfaces of the spring, internal cavities, etc., that are forward of the stop section 32.

Various features or elements appear in Figs. 3 and 3a that have not been specifically identified above. Those features or elements are substantially identical to the items in Figs. 1 and 2 that have corresponding reference numerals --i. e.., numerals that differ only by addition of the prefix "1" in Figs. 3 and 3a.

Figs. 4 through 6 illustrate another embodiment of my invention. Here the corresponding parts have reference numerals varying by addition of the prefix "2".

In the embodiment of Figs. 4 through 6, the latch is triggered by pressing the rear end of the handle against any surface: a tabletop, the user's arm, or even part of the patient's arm. This form of my invention may be preferably in environments where a tabletop or other suitable positive-actuating surface is available.

It may be found unsatisfactory, however, where only softer surfaces such as bedding or the patient's body can be used. Another aspect of this embodiment that may be found undesirable is a slightly greater outside diameter of the grip surface

211.

The carrier block 231-232 of Figs. 4 through 6 is generally like that in Fig. 1. Here, however, the spring 261 seats directly against the inside surface of the nosepiece 222.

A latch cylinder 241 is inserted through the rear of the handle 210 into a bore 212. Roughly the front third or half of the latch cylinder 241 is split into two (or more) flexible fingers 245, which terminate at their forward ends in lips or flanges 246 that point radially outward.

The bore 212 inside the handle 210 is enlarged, proceeding toward the front of the device, in two definite steps. The first step, outward to the bore 212c (Figs. 5 and 6), provides a ledge for capture of the lips or flanges 246 to deter the latch cylinder 241 from falling rearward out of the handle 211.

When the fingers are in position against the bore 212c, the carrier-block frustoconical stop section 232 is pressed by the spring 261 against pretrigger stop surfaces formed by the insides of the ends of the fingers 245. This is the pretrigger condition shown in Fig. 4.

The second step, outward to the bore 212a, provides radial escape room for expansion of the fingers away from the carrier-block step section 232. Thus when the rear end of the latch cylinder 241 is pressed forwardly from its Fig. 4 position, it at first drives the carrier block and needle very slightly forward until the lips 246 reach the second step. The lips 246 then spring outward against the bore 212a, to their positions shown in Fig. 5.

The carrier-block stop section 232 is no longer obstructed by the pretrigger stop surfaces formed by the ends of the fingers 245. The block 231, 232 with the needle 150 is accordingly propelled rearward by the coil spring 261.

Fig. 5 shows the block 231, 232 and needle 250 an instant after the beginning of this motion. As illustrated they are just started rearward into the bore 242 of the latch cylinder 241.

Eventually the carrier-block stop section 232 engages the inner stop surface 244 at the rear of the latch cylinder 241, as shown in Fig. 6. The needle is then retained fully retracted within the handle 210 and latch cylinder 240.

The embodiment of Figs. 7 and 8 may be useful where a solid (that is, not hollow) needle 350 can be employed. Such needles, as previously mentioned, are acceptable if it is not necessary to allow for the desirability of pretriggering temporary fluid connection through the needle.

Some cost saving is effected by using a needle that is solid, and this saving can be further enhanced by using a mechanism that need not be fluid-tight and sanitary inside. One such mechanism is shown in Figs. 7 and 8.

Here the needle carrier block is a simple spool --a short necked-down barrel 331 separating two flanges 332, 333. To put it another way, a circumferential groove 331 is formed partway along the carrier-block barrel 331, 332.

A needle-retraction sleeve 340 slides on the outside of the cylinder 311. A retraction-actuator pin 342 extends inwardly from the retraction sleeve 340, through a slot 311s in the wall 311, 312 of the handle 310, and into the groove 331 in the carrier block 330.

Before and during insertion of a cannula with the Fig. 7 and 8 embodiment, firm detents (not shown) hold the block 330, needle 350 and sleeve 340 at the front of the handle 310. This condition, illustrated in Fig. 7, continues until the cannula is in place within the patient's body.

Then the user of the device holds the rear end of the handle 310 firmly against a solid surface, and manually pulls the retraction sleeve 340 rearward out of the detents. As the user moves the retraction sleeve, its retraction pin 342 forces the carrier block 330 and needle to move correspondingly rearward.

When the sleeve 340 is operated fully to the rear of the handle 310, positive-acting ratchet-type detents come into play to prevent the sleeve from being advanced. These detents thus lock the needle in its retracted position.

Yet another embodiment appears in Figs. 9 and 10. Whereas the movable latch elements of Figs. 1 through 6 are mounted to the respective handles of the illustrated devices, and there is no latch as such in Figs. 7 and 8, the movable latch elements of Figs. 9 and 10 are mounted to the carrier block.

More particularly, radially extending latch ears 435 (Fig. 10) are restrained within guide holes in the outside of the carrier block, but biased radially outward by springs 436. These latch ears 435 engage thickened portions 412c of the handle wall 411, 412, preventing rearward motion of the carrier block 431 and needle.

After use, the user squeezes latch-actuator fingers 446, at opposite sides of the handle exterior 411. The tips of these fingers are formed with small inwardly extending bosses 447.

When the user squeezes the fingers 446 inward, the bosses 447 force the latch ears 435 inward against the action of the springs 436, disengaging the ears from the thickened wall portions 412c. A coil spring 461 then propels the carrier block and needle rearward as in the embodiments of Figs. 1 through 6.

After passing the thickened wall portions 412c, the latch ears are again biased radially outward from the carrier block. Accordingly, when the block reaches the rear end of the handle and the needle

is fully sheathed, the latch ears engage the rear stops 414 to halt the retraction.

Figs. 11 and 12 are included to indicate in a schematic way that carrier-block-and-spring embodiments of my invention may generally include any mechanical arrangement of the general character shown. In these drawings, a releasable latch element 544 temporarily secures a carrier block 530 at the forward end of a handle-cylinder 511.

In the general arrangement shown, the sharp end 552 of a needle projects through a forward aperture 523 and out of the forward end 521 of the handle. A spring 561 biases the carrier block 530 rearward.

Any such configuration (as well as others not encompassed within the general relationships illustrated) is currently believed to be within the scope of my invention. It is immaterial whether movable latch elements are mounted to the carrier block 530, the handle 510, or both.

Generally speaking, the overall length of any such device will be the sum of two distances. The first of these is twice the length of the narrow part of the cannula --a distance that is essentially fixed by the needed length of the cannula.

The second distance is the distance from the front of the nosepiece to the rear of the needle. The distance from the front of the nosepiece to the rear of the needle equals the sum of the lengths of the cannula hub, the fully compressed spring, and the rear stop surface of the carrier block.

These lengths, generally speaking, are controllable to some degree through careful design. They should be minimized.

Figs. 13, 13a and 13b show a configuration in which two latch elements 638, 644 are respectively mounted to the carrier block 630 and handle wall 611. Neither element 638 or 644 moves radially or longitudinally.

An actuator mechanism is present, however, that provides relative rotation of the block 630 and handle. When this mechanism is operated, it offsets the two elements 638, 644 and releases the carrier block 630 for retraction.

The actuator mechanism includes a pair of helical surfaces 637 that are cut into opposite sides of the rear periphery of the carrier block 630. Necessary relief for these structures is provided by planar end walls 638 and cylindrical inside walls 639 as illustrated.

The actuator mechanism also includes a pair of actuator pins 641 that are forced through apertures in an end wall (not shown) of the handle, and against the helical surfaces. When the user operates the actuator pins 641, the block rotates within the handle as suggested by the arrow 649 in Fig. 13b.

One other embodiment of my invention is shown in Figs. 14 and 15. Here the movable latch elements are flexible fingers 744 formed as cutouts from portions of the handle wall 711 itself. These latch fingers 744 engage the rear side of the carrier block 730, restraining it against action of the coil spring 761.

To release the block 730 for retraction, the user pushes forwardly on an actuator button 749 at the rear of the handle. This may alternatively be accomplished, as described with regard to Figs. 4 through 6, by pushing the handle rearward against a reaction surface.

Here the button 749 slides actuator pins 741 forward, relative to the handle, within guideways 712d, 712e. The actuator pins force the latch fingers 744 radially outward, releasing the block 730. As noted in the description of figures, these drawings are merely schematic.

It will be understood that the foregoing disclosure is intended to be merely exemplary, and not to limit the scope of the invention --which is to be determined by reference to the appended claims.

Claims

1. A safety device for use in inserting a cannula into a patient and for thereafter protecting people from contact with portions of the device that have been within the patient; said device comprising:

a needle for piercing such patient and for guiding and carrying such a cannula into place within such patient, said needle having a shaft with at least one sharp end;

a hollow handle adapted to enclose at least the sharp end of the needle beyond reach of such people's fingers;

means for securing the shaft to the handle, with the sharp end projecting from the handle; and

means for releasing the securing means and for substantially permanently retracting the sharp end of the needle into the handle and beyond reach of such people's fingers;

said releasing and retracting means being manually actuable by a simple unitary motion, of amplitude that is substantially shorter than the shaft of the needle.

2. The safety device of claim 1, wherein:

the handle defines an aperture that is small compared with such people's fingers but large enough for passage of the needle.

3. The safety device of claim 1, wherein the releasing and retracting means comprise:

a trigger mechanism operable from outside the handle.

4. The safety device of claim 1, wherein the releasing and retracting means comprise:

means for positively biasing the sharp end of the needle toward retraction into the handle.

5. The safety device of claim 4, wherein:

the biasing means also operate to retain the sharp end of the needle retracted within the handle.

6. The safety device of claim 1, wherein the securing means comprise:

a block fixed to and extending from the needle, and adapted to be restrained within the handle with the sharp end of the needle projecting from the handle; and adapted for motion within the handle, responsive to the releasing and retracting means, to withdraw the needle into the handle.

7. The safety device of claim 1, for use with such a cannula that has a standard-size rear tubing fitting, for passage of liquids between the patient's body and equipment outside the patient's body after the needle is removed from the patient; and wherein:

the needle is hollow, for passage of such liquids while the needle is within such patient; and

the hollow handle has a standard-size rear fitting for attachment of such tubing while the needle is within the patient;

whereby such liquids pass between the tubing and the patient by way of the needle and the handle rear fitting temporarily, while the needle is within the patient.

8. The safety device of claim 1, wherein:

the releasing and retracting means are actuable by one hand of a user of the device.

9. The safety device of claim 1, wherein:

the releasing and retracting means are manually actuable by a user of the device, employing just one hand and without looking at the device.

10. The safety device of claim 1, in further combination with:

such cannula.

11. A safety device for use in inserting an intravenous cannula into a patient's blood vessel and for thereafter protecting people from contact with portions of the device that have been within the patient; said device comprising:

a hollow needle for piercing such patient and for guiding and carrying such a cannula into place within such patient's blood vessel, said needle having a hollow shaft with at least one sharp end;

a hollow handle that defines an aperture which is small compared with such people's fingers but large enough for passage of the needle, and that is otherwise adapted to enclose at least the sharp end of the needle:

a block fixed to and extending from the needle, and restrained within the handle with the sharp end of the needle projecting out of the handle through the aperture, and adapted for motion within the handle to withdraw the needle into the handle; and

a trigger mechanism, actuable from outside the handle for releasing the block, and including positive biasing means for forcibly moving the block within the handle to substantially permanently retract the sharp end of the needle into the handle and beyond reach of such people's fingers.

12. The safety device of claim 11, wherein:

the trigger mechanism is actuable by one hand of a user of the device.

13. The safety device of claim 11, wherein:

the trigger mechanism includes a projection from the handle, adapted for manual actuation by a user of the device to release the block.

14. The safety device of claim 11, wherein:

a guideway is defined within the handle to guide the block rearward from the aperture.

15. The safety device of claim 11, wherein:

a stop is defined within the handle, opposite the aperture, for halting the motion of the block after actuation of the trigger mechanism;

whereby the block and needle are retained within the handle.

16. The safety device of claim 11, for use with such a cannula that has a standard-size rear tubing fitting, for passage of liquids between the patient's body and equipment outside the patient's body after the needle is removed from the patient; and wherein::

the needle is hollow, for passage of such liquids while the needle is within such patient; and

the hollow handle has a standard-size rear fitting for attachment of such tubing while the needle is within the patient;

whereby such liquids pass between the tubing and the patient by way of the needle and the handle rear fitting temporarily, while the needle is within the patient.

17. The safety device of claim 11, in further combination with:

such cannula.

18. The safety device of claim 11, further comprising:

a stop element extending laterally from the block;

means for biasing the stop element outward from the block; and

a stop surface, defined within the handle, that engages the stop element to restrain the block from moving within the handle; and

wherein the handle has an external surface: and

the trigger mechanism includes a manually operable release member, accessible at or through the external surface of the handle, for forcing the

laterally extending stop element inward against the action of the outward biasing means to release the block.

19. The safety device of claim 11, further comprising:

a stop element extending laterally within the handle;

means for biasing the laterally extending stop element inward from the handle; and

a stop surface, defined on the block, that engages the laterally extending stop element to restrain the block from moving within the handle; and

wherein the handle has an external surface; and

the trigger mechanism includes a manually operable release member, accessible at or through the external surface of the handle, for forcing the laterally extending stop element outward against the action of the inward biasing means to release the block.

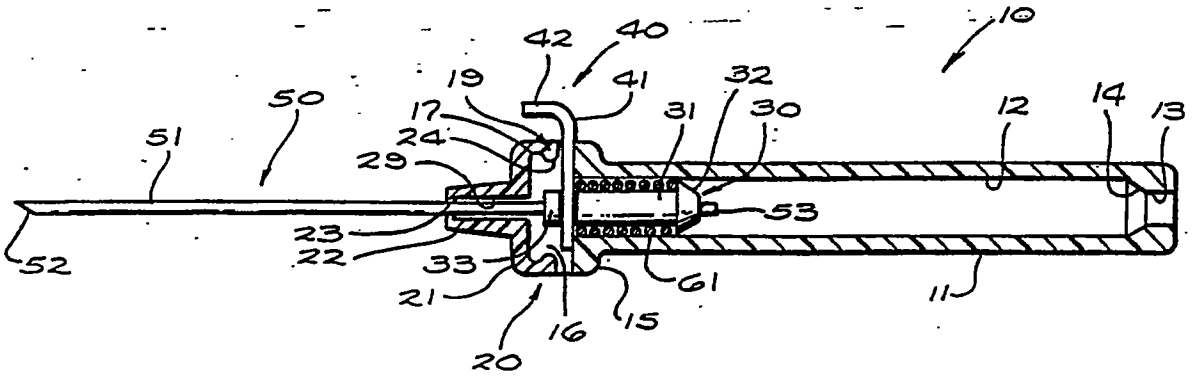
20. The safety device of claim 11, further comprising:

stop elements respectively defined within the handle and on the block, for engaging each other over a limited range of angular positions of the block within the handle to restrain the block from retracting the needle; and

wherein the handle has an external surface; and

wherein the trigger mechanism includes a manually operable release member, accessible at or through the external surface of the handle, for forcibly rotating the block out of said range of angular positions to release the block.

FIG. 1



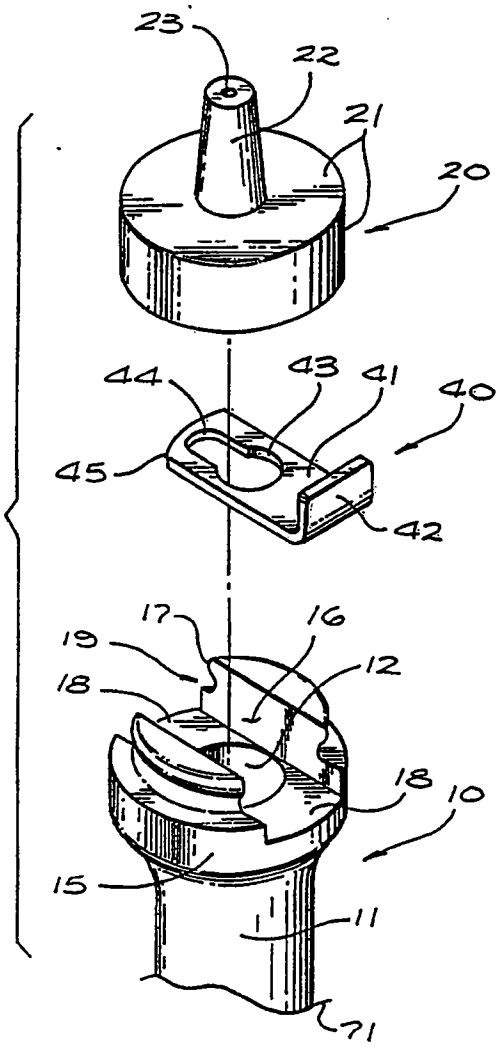


FIG. 2

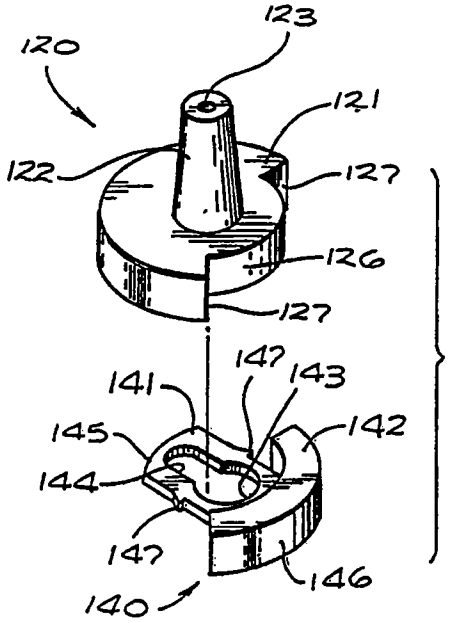


FIG. 3

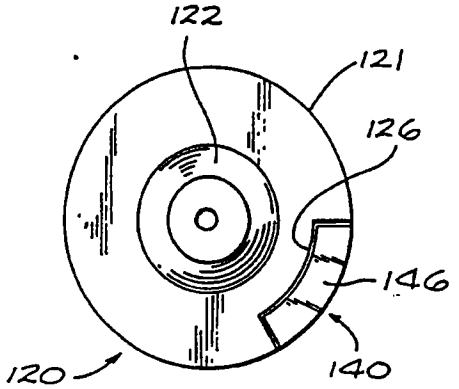


FIG. 3a

FIG. 4

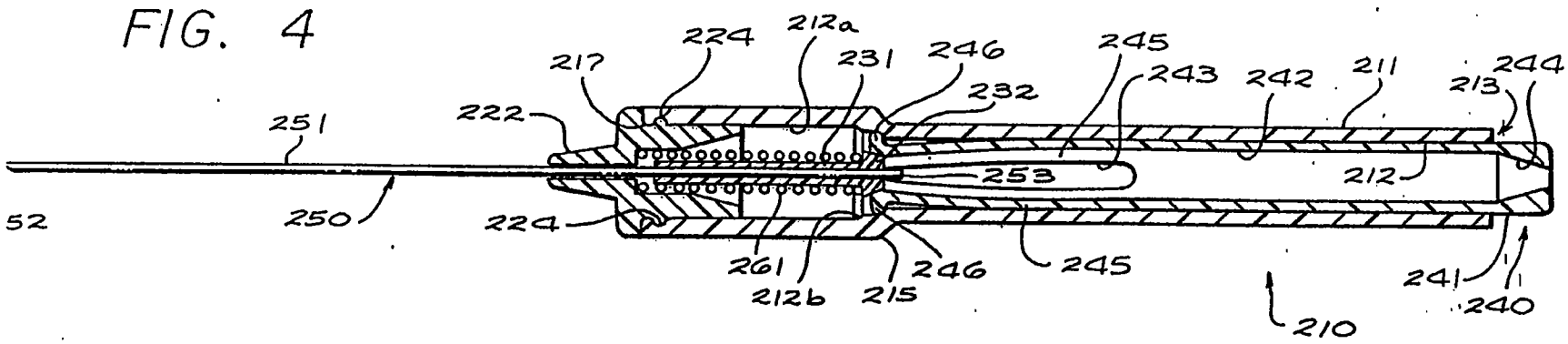


FIG. 5

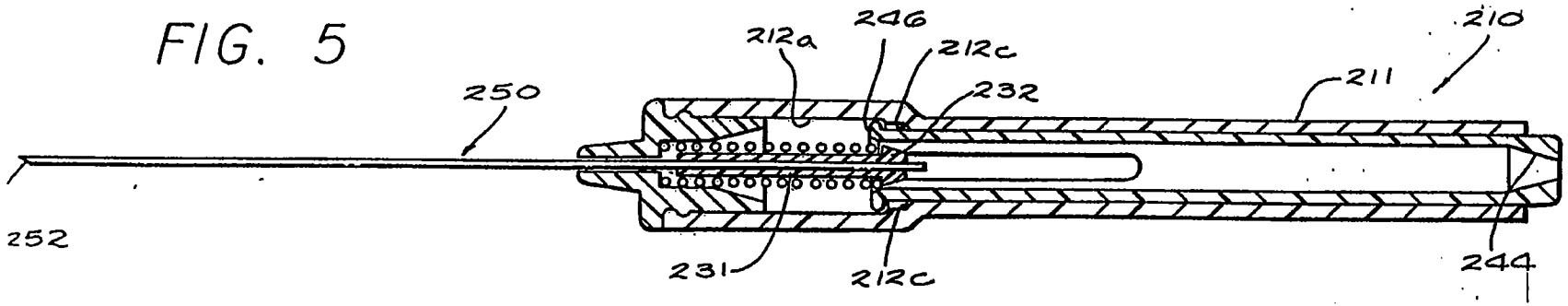


FIG. 6

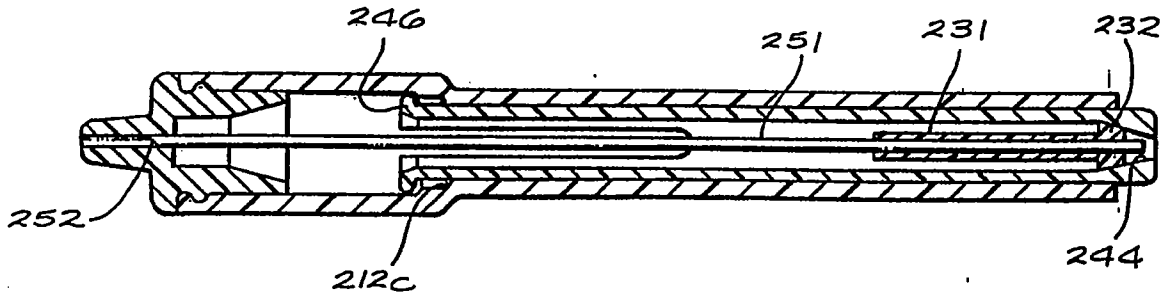


FIG. 7

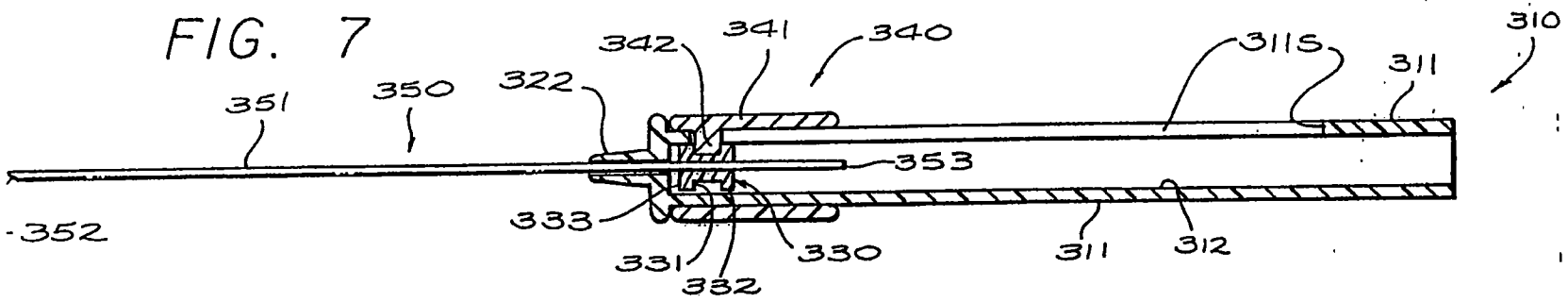
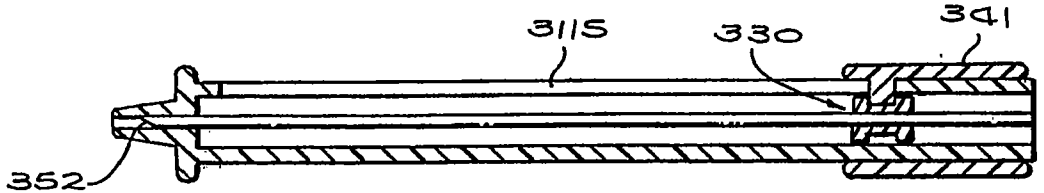


FIG. 8



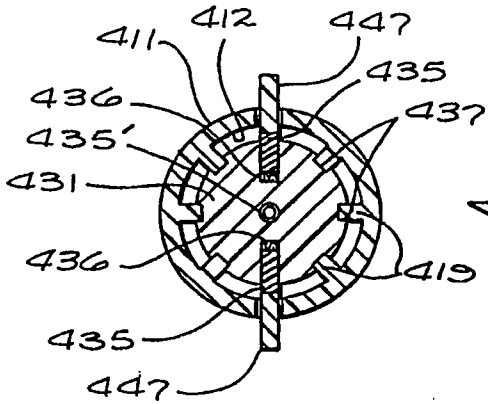


FIG. 10

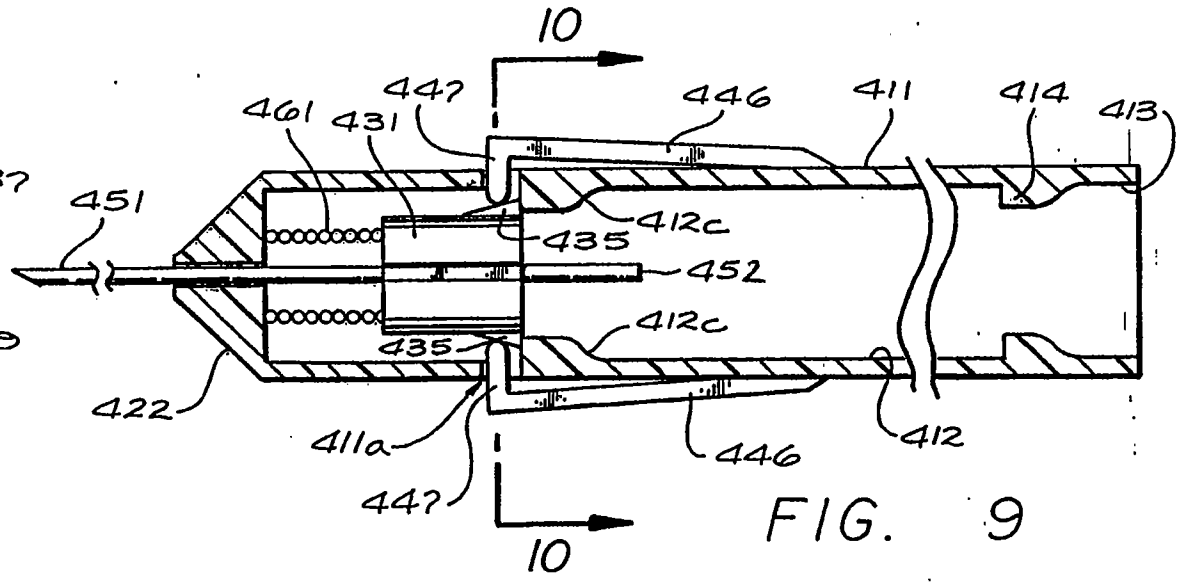


FIG. 9

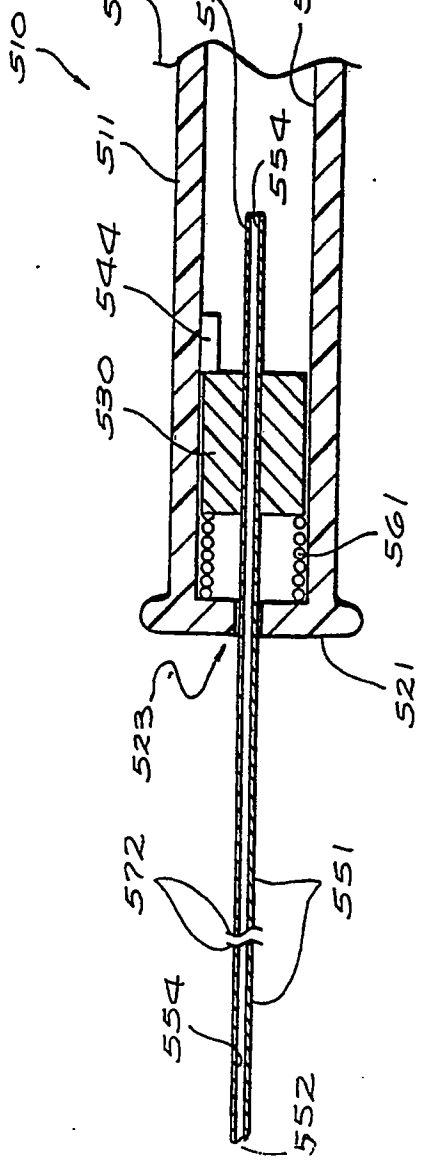


FIG. 11

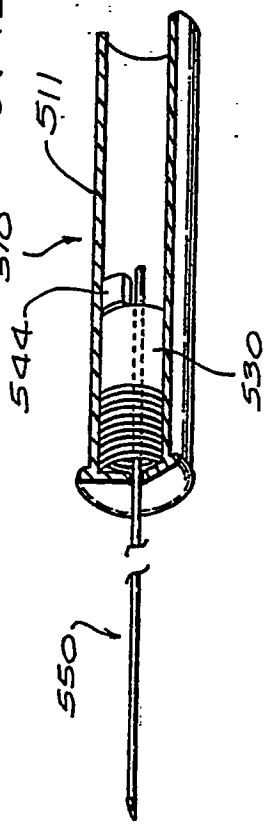


FIG. 12

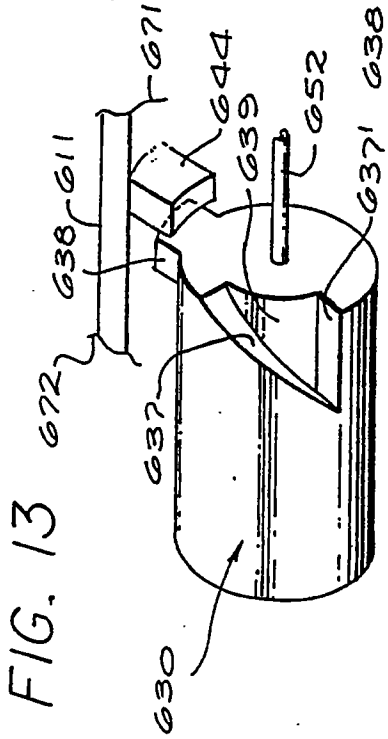


FIG. 13

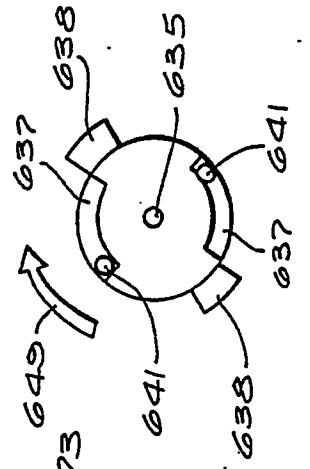


FIG. 13b

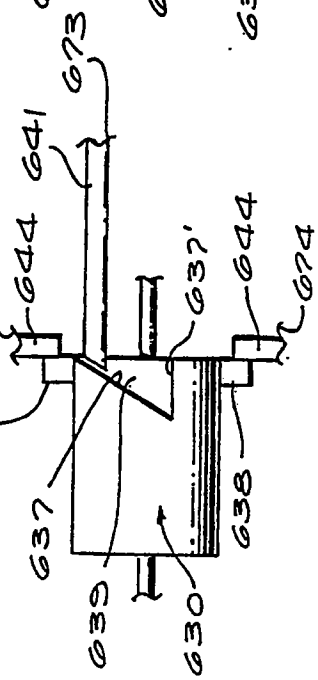


FIG. 13a

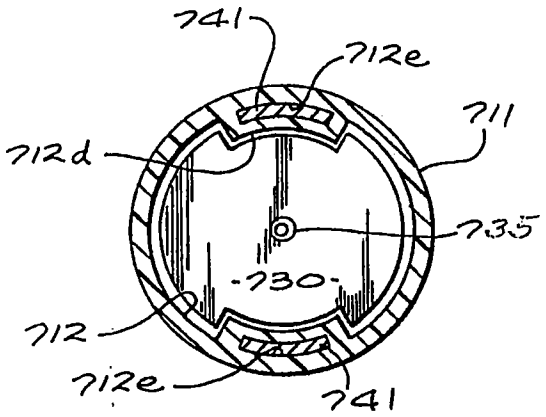


FIG. 15

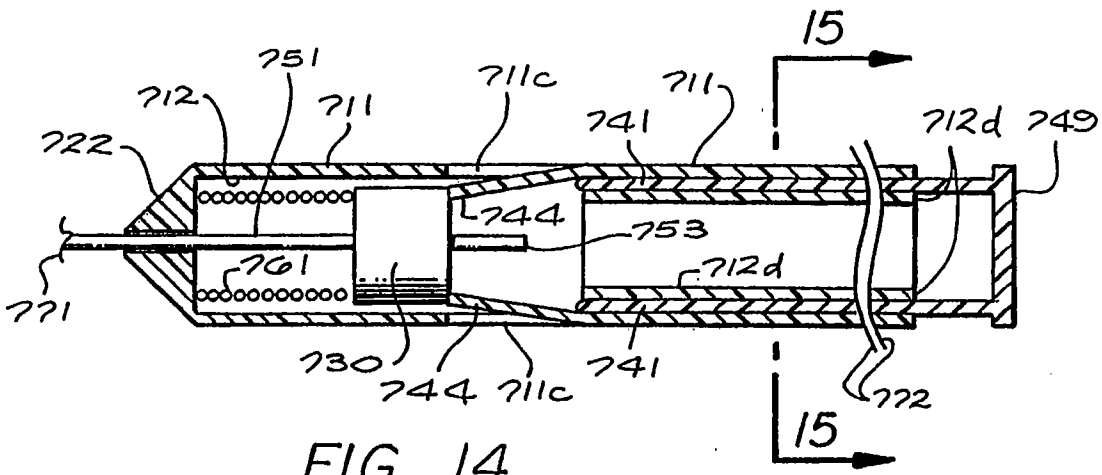


FIG. 14

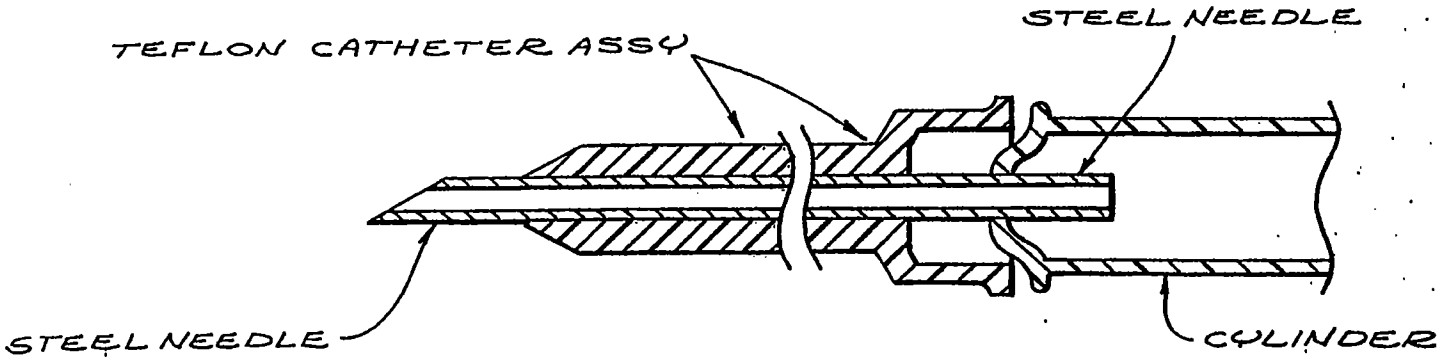


FIG. 16 PRIOR ART

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 88 30 3687

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
Y	WO-A-8 702 254 (PHYSIONIC GES. FÜR MEDIZIN- UND SYSTEMTECHNIK GmbH) * Page 15, line 21 - page 16, line 12; figures 13,14 * ---	1-6,8-15,17,19	A 61 M 25/00
Y	US-A-4 292 970 (HESSION Jr.) * Column 2, lines 10-21; column 4, lines 30-39; figures 5-8 * ---	1-6,8-15,17,19.	
A	US-A-4 488 545 (SHEN) * Abstract; figures 1,2 * ---	1,4,5,8-10	
A	GB-A-1 446 767 (T. AKJYAMA) * Claims 1-3; figures 3,5,6 * ---	1-6,8-10	
A	US-A-3 856 010 (MOOREHEAD et al.) * Column 3, lines 16-22; figure 1 * ---	7,16	
A	US-A-4 695 274 (FOX) * Column 3, lines 52-60; figures 1,3 * -----	20	

TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	20-07-1988	CLARKSON P.M.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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(54) Closed system intravenous catheter.

(57) An improved intravenous catheter is disclosed which, when properly positioned within a vein, provides a closed system catheter. The closed system intravenous catheter comprises a catheter having a tapered portion (20), a hub portion (36) and a fluid-flow passageway (28) extending therethrough. A fluid-impermeable elastomeric gasket member (30) is disposed within the hub portion of the catheter for sealing the hub portion and the fluid-flow passageway of the catheter. A skin-penetrating stylet (37) of a stylet assembly (32) extends through the elastomeric gasket member and the fluid-flow passageway of the catheter so hat a puncture tip (38) on a proximal end of the skin-penetrating stylet extends outwardly from the tapered portion of the catheter. An air-permeable, liquid-impermeable vent assembly (80) is connected to an observation chamber (74) of the stylet assembly so that blood flow into a flashpoint cavity (76) defined by the observation chamber can be observed and controlled. The vent also permits auxiliary equipment to be connected without leakage of blood. A retractable sheath (130) for the skin-penetrating stylet is also provided which covers the skin-penetrating stylet when same is removed from the catheter so as to minimize exposure of health care workers to the potentially contaminated puncture tip of the skin-penetrating stylet.

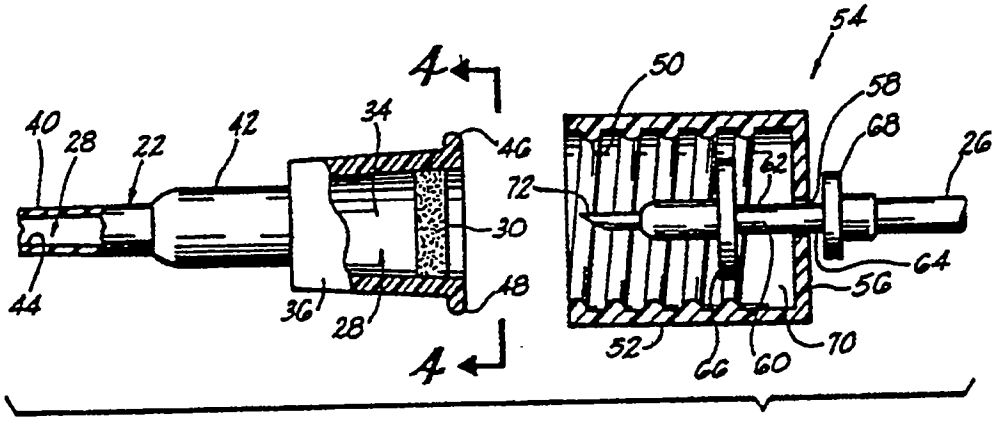

Fig. 3

EP 0 451 040 A1

1. Field of the Invention.

The present invention relates generally to catheters used to administer intravenous, arterial or central venous fluids, and more particularly but not by way of limitation, to an improved closed system angiocatheter.

2. Discussion of Prior Art.

Catheters are used to administer intravenous, arterial or central venous fluids to a patient. One of the most commonly employed catheters is the angiocatheter which comprises a tapered catheter having a fluid-flow passageway extending therethrough and a skin-penetrating stylet. The skin-penetrating stylet is provided with a sharpened puncture tip and an observation chamber having a flashpoint cavity therein. When the skin-penetrating stylet is positioned within the fluid-flow passageway of the catheter, the puncture tip extends beyond the catheter so that the puncture tip can puncture the skin and vein prior to placement of the catheter into the vein. Thus, blood can flow through the skin-penetrating stylet and into the flashpoint cavity to indicate to the health care worker that the angiocatheter is properly positioned within the vein. Further confirmation that the angiocatheter has been properly positioned in the vein can be achieved by partially "backing off" or removing the skin-penetrating stylet so that blood flow can continue through the fluid- flow passageway of the catheter.

When blood flow indicates proper positioning of the catheter, and the skin-penetrating stylet is removed therefrom, intravenous tubing can be connected to the catheter so that intravenous fluids can be administered to the patient. To prevent backflow of blood, the health care worker places a thumb against the vein to tamponade the vein and thereby restrict blood flow into the catheter.

Because it is desirable to maintain the catheter in place, even when not administering an intravenous fluid, externally disposed cap members have heretofore been employed to seal the catheter in order to prevent infectious germs and viruses from entering the patient's bloodstream through the catheter. As can be appreciated, germs and viruses often enter the bloodstream because of the manipulation required in attempting to remove and reseal the catheter which results in potential infection. Further, blood often leaks through the catheter and into contact with the attending health care worker so that the health care worker is exposed to potentially infectious blood. In addition, the blood gets onto the bedding of the patient prior to capping of the catheter. This blood leakage can be dangerous, especially if the blood is infectious, resulting in potential transfer of the infection. In addition, blood leakage through the catheter results in unnecessary work, such as changing the bedding of the patient. Thus, leakage of blood through the catheter is very undesirable and potentially dangerous.

Prior attempts to provide a "closed system" catheter which would prevent germs and viruses from entering the patient's bloodstream, as well as prevent leakage of blood through the catheter after removal of the skin-penetrating stylet or prior to the attachment of intravenous tubes and the like, have not been successful. Thus, the need remains for the development of a closed system catheter which would enable one to withdraw the skin-penetrating stylet from the catheter without leakage of blood through the implanted catheter, and which would permit one to connect and disconnect intravenous tubing to the catheter without exposing the health care worker, as well as auxiliary personnel such as laundry workers and the like, to potentially infectious blood; while at the same time preventing exposure of the internal portion of the catheter, and thus the patient, to potentially infectious germs or viruses present in the surrounding environment. Further, in order to reduce the number of punctures which a patient is subjected to, it would be highly desirable if one could provide an improved angiocatheter which prevents back flow of blood and yet readily permits the health care worker to obtain blood samples through the catheter without leakage of blood or the necessity of capping or removing a cap from the catheter. It is to such an improved closed system catheter that the present invention is directed.

Summary of the Invention

According to the present invention, an improved intravenous catheter is provided which, when properly positioned within a vein, provides a closed system catheter. That is, once the catheter is implanted in a vein, the catheter is effectively self- sealing and the catheter not only prevents leakage of blood therethrough, but also effectively closes off the internal portion of the catheter to the external surrounding environment so that germs and viruses cannot enter the patient's bloodstream through the implanted catheter.

Broadly, the closed system intravenous catheter of the present invention comprises a catheter having a tapered portion, a hub portion and a fluid-flow passageway extending therethrough. A fluid-impermeable elastomeric gasket member is disposed within the hub portion of the catheter for sealing the hub portion and the fluid-flow passageway of the catheter. A skin-penetrating stylet of a stylet assembly extends through the elastomeric gasket member and the fluid-flow passageway of the catheter so that a puncture tip on a proximal end of the skin-penetrating stylet extends outwardly from the tapered portion of the catheter. The puncture tip of the skin-penetrating stylet permits one to produce a puncture site in the

patient's skin so that the tapered portion of the catheter can be positioned in a vein without great discomfort to the patient.

To insure that the catheter has been properly placed in the vein, the stylet assembly is provided with an observation chamber connected to a distal end of the skin-penetrating stylet. The observation chamber, which defines a flashpoint cavity, is connected to an air-permeable, liquid-impermeable vent assembly so that the flow of blood into the flashpoint cavity can be observed and effectively controlled. The vent assembly not only permits one to control the flow of blood into the flashpoint cavity, but also permits one to operably connect auxiliary equipment, such as a blood sampling device, to the catheter without leakage of blood.

In order to accomplish the before-mentioned dual function the vent assembly comprises an air-permeable, liquid-impermeable frit supported on the observation chamber of the stylet assembly and a vent stylet connected to the observation chamber of the stylet assembly so as to openly communicate with the flashpoint cavity. A fluid-impermeable elastomeric cover member is connected to the frit such that the cover member is positionable over the vent stylet. The air-permeable, liquid-impermeable frit cooperates with the vent stylet and the elastomeric cover member so that blood is permitted to flow into the flashpoint cavity of the observation chamber, while preventing the flow of blood from the flashpoint cavity through the vent stylet until such time as auxiliary equipment has been properly connected to the observation chamber of the stylet assembly.

To connect auxiliary equipment, such as a blood sampling device to the angiocatheter of the present invention, the fluid-impermeable elastomeric cover member is compressed by the auxiliary equipment so that a puncture tip of the vent stylet penetrates through the elastomeric cover member and fluid communication is established between the stylet assembly and the auxiliary equipment via the vent stylet. Because of the resilient nature of the fluid-impermeable elastomeric cover member, when the auxiliary equipment is disengaged from the vent stylet, the cover member returns to a non-compressed condition and effectively seals the vent stylet so that the fluid-tight seal is reestablished.

To prevent exposure of a health care worker to inadvertent puncture by the vent stylet during placement of the angiocatheter into the vein of a patient, as well as to protect the vent stylet, a closure member or cap is positionable over the vent assembly so as to effectively encapsulate the vent stylet.

To prevent exposure of a health care worker from inadvertent puncture by the skin-penetrating stylet used to puncture the skin and vein for vein entry of the catheter after the skin-penetrating stylet has been removed from the catheter, a protective sheath is advantageously incorporated into the stylet assembly of the angiocatheter so as to effectively encapsulate the puncture tip of the skin-penetrating stylet.

An object of the present invention is to provide an improved intravenous catheter.

Another object of the present invention, while achieving the before stated object, is to provide a closed system intravenous catheter which prevents undesired leakage of blood therethrough and which prevents exposure of health care workers to potentially infectious blood.

Another object of the present invention, while achieving the before stated objects, is to provide a multi-purpose closed system intravenous catheter which is easy to use and which reduces the number of puncture sites required in the treatment of a patient.

Yet another object of the present invention, while achieving the before stated objects, is to provide an improved closed system catheter which is simple in construction and economical to manufacture.

Other objects, advantages and features of the present invention will become apparent from the following detailed description when read in conjunction with the appended claims.

Brief Description of the Drawings

FIG. 1 is a pictorial illustration of an angiocatheter of the present invention disposed within a vein of a patient's arm.

FIG. 2 is an enlarged side view, partially in cross section, of the angiocatheter of the present invention having a closure cap supported on an observation chamber so as to be disposed in a covering position over a vent assembly of the angiocatheter.

FIG. 3 is an enlarged side view, partially in cross section, of the catheter of the angiocatheter of the present invention illustrating auxiliary equipment positioned for attachment to the catheter.

FIG. 4 is an enlarged view of the catheter of the angiocatheter of the present invention, taken along the line 4-4 of FIG. 3.

FIG. 5 is an enlarged side view, partially in cross section, of the angiocatheter of the present invention illustrating a vent assembly for the observation chamber of the stylet assembly wherein the closure cap is disposed in a covering position over the vent assembly.

FIG. 6 is an enlarged, fragmental side view, partially in cross section, of the vent assembly of the angiocatheter of the present invention wherein an elastomeric stylet covering member of the vent assembly is disposed over a vent stylet.

FIG. 7 is an enlarged, fragmental side view, partially in cross section, of a blood sampling device operably connected to the angiocatheter of the present invention.

FIG. 8 is an enlarged, fragmental side view, par-

tially in cross section of a protective sheath for the skin-penetrating stylet of the angiocatheter of the present invention wherein the protective sheath is in a retracted, compressed position when the skin-penetrating stylet is disposed within the catheter.

FIG. 9 is an enlarged, fragmental side view, partially in cross section of the protective sheath for the skin-penetrating stylet of the angiocatheter of the present invention wherein the protective sheath is in an extended skin-penetrating stylet covering position.

FIG. 10 is an enlarged, fragmental side view, partially in cross section of a second embodiment of a protective sheath of the skin-penetrating stylet of the angiocatheter of the present invention.

Detailed Description

Referring to the drawings, and more particularly to FIG. 1, an improved angiocatheter 10 of the present invention is illustrated positioned within a vein 12 in a patient's arm 14. As will be more fully described hereinafter, the angiocatheter 10 permits one to produce a puncture site 16 in a patient's skin 18 and the underlying vein 12 so that a tapered proximal end portion 20 of a catheter 22 can be positioned within the vein 12 without great discomfort to the patient, while at the same time reducing slippage and coring.

Auxiliary equipment, such as a Vacutainer® brand blood sampling device 24 (FIG. 7), can be connected to the angiocatheter 10 without the need of puncturing the patient's skin a second time to produce a second puncture site, or a standard intravenous needle by be used to connect intravenous fluid tubing 26 (FIG. 3) to the catheter 22 so that intravenous fluids can be administered to the patient via the catheter 22. Further, the unique design of the catheter 22 also permits one to administer repeated injections using an injection needle connected to a syringe.

The term "closed system catheter" as used herein is understood to mean that once the catheter 22 is properly implanted in the vein 12 a fluid-flow passageway 28 which extends through the catheter 22 (FIG. 3) is effectively self-sealing so as to prevent leakage of blood therethrough without the requirement of an external cap member. Thus, the fluid-flow passageway 28 of the catheter 22 is effectively sealed to the surrounding environment so that air, germs and viruses cannot enter the patient's blood- stream through the fluid-flow passageway 28 of the implanted catheter 22.

Referring now to FIGS. 2-5, the angiocatheter 10 comprises the catheter 22, a resilient, fluid-impermeable gasket member 30 and a stylet assembly 32. The resilient gasket member 30, which is fabricated of a substantially fluid-impermeable elastomeric material, is supported with a cavity 34 defined by a hub 36 of the catheter 22 so that the gasket member 30 effectively seals the fluid-flow passageway 28 of the catheter 22 to both air and liquid.

A skin-penetrating stylet 37 of the stylet assembly 32 is slidably disposed within the fluid-flow passageway 28 of the catheter 22 so as to penetrate the resilient gasket member 30. A puncture tip 38 of the skin-penetrating stylet 37 extends outwardly from the tapered proximal end portion 20 of the catheter 22 substantially as shown in FIG. 2. Thus, when positioning the catheter 22 into the vein 12 the puncture tip 38 of the skin-penetrating stylet 37 punctures the puncture site 16 on the patient's skin 18, and the underlying vein 12, so that the tapered proximal end portion 20 of the catheter 22 can be positioned within the vein 12.

When the catheter 22 has been positioned within the vein 12 and the stylet assembly 32 removed therefrom, the resilient gasket member 30 effectively reseals the place of penetration of the skin-penetrating stylet 37 in the resilient gasket member 30 so as to provide a fluid-impermeable seal for the fluid-flow passageway 28 of the catheter 22. Thus, the resilient gasket member 30 prevents blood leakage through the fluid-flow passageway 28 of the catheter 22, while at the same time closing off the fluid-flow passageway 28 from contact with the outward surrounding environment or atmosphere.

As more clearly shown in FIGS. 2 and 3, the catheter 22 comprises the hub 36 and a tapered body member 40. The hub 36 and the tapered body member 40 can be fabricated of any suitable polymeric material; and the hub 36 and the tapered body member are desirably of unitary construction.

The tapered body member 40 is an elongated member having the tapered proximal end portion 20, a distal end portion 42 and a fluid-flow bore 44 extending therethrough. The hub 36 is supported by the distal end portion 42 of the tapered body member 40 such that the cavity 34 of the hub 36 openly communicates with the fluid-flow bore 44 of the tapered body member 40. Thus, the cavity 34 of the hub 36 and the fluid-flow bore 44 of the tapered body member 40 cooperate to define the fluid-flow passageway 28 of the catheter 22.

To assist in the connection of auxiliary equipment such as the intravenous tubing 26 to the catheter 22 so that intravenous fluid can be administered to the patient via the catheter 22 when the stylet assembly 32 has been removed from the catheter 22, the hub 36 of the catheter 22 is further provided with a pair of oppositely disposed, outwardly extending tab members 46, 48 adapted to operably engage mating threads 50 disposed within an open first end 52 of an intravenous fluid tubing connector 54 (see FIG. 3).

The connector 54, a substantially cylindrical-shaped member, in addition to the open first end 52, is characterized as having an opposed second end 56. The opposed second end 56 is provided with a centrally disposed aperture 58 adapted to receive an elon-

gated, cylindrical-shaped tubular coupling member 60.

The coupling member 60 (which is slidably disposed through the aperture 58) is provided with a first end 62 and an opposed second end 64. The first end 62 of the coupling member 60 extends inwardly into the connector 54; and the opposed second end 64 of the coupling member 60 is positioned exterior the connector 54 substantially as shown in FIG. 3. To restrict the to and fro movement of the tubular coupling member 60 through the aperture 58, the coupling member 60 is provided with a pair of spatially disposed stop members 66 and 68, each of which has a diameter greater than the diameter of the aperture 58. As shown in FIG. 3, the stop member 66 is connected to the coupling member 60 so as to be disposed within a hollow interior portion 70 of the connector 54; and the stop member 68 is connected to the coupling member 60 so as to be disposed exterior the connector 54. Thus, when the stop member 68 abuttingly engages the opposed second end 56 of the connector 54, the movement of the coupling member 60 in the "to" direction is halted; whereas, when the stop member 66 abuttingly engages the opposed second end 56 of the connector 54, the movement of the coupling member 60 in the "fro" direction is halted.

In order to establish fluid communication between the intravenous fluid tubing 26 and the fluid-flow passageway 28 of the catheter 22, an intravenous tubing stylet or needle 72 is connected to the first end 62 of the coupling member 60; and the intravenous fluid tubing 26 is connected to the opposed second end 64 of the coupling member 60. Thus, fluid communication is established between the intravenous tubing stylet or needle 72 and the intravenous fluid tubing 26. As can be appreciated, in order to establish fluid communication between the intravenous tubing stylet 72 and the fluid-flow passageway 28 of the catheter 22, the intravenous tubing stylet 72 must have a sufficient length so that when the connector 54 is threadably connected to the hub 36 of the catheter 22, the intravenous tubing stylet 72 penetrates the resilient gasket member 30 and openly communicates with the fluid-flow passageway 28 of the catheter 22.

As shown in FIGS. 2 and 5, the stylet assembly 32, in addition to the skin-penetrating stylet 37, comprises an observation chamber 74 which defines a flashpoint cavity 76 therein. The flashpoint cavity 76 is in fluid communication with a fluid-flow bore 78 of the skin-penetrating stylet 37 so that blood flow through the skin-penetrating stylet 37 via the bore 78 can be observed in the flashpoint cavity 76. A vent assembly 80 is connected to and supported by the observation chamber 74 so that the flow of blood into the flashpoint cavity 76 cannot only be observed therein, but can be effectively controlled by the vent assembly 80. Further, as will be set forth in more detail hereinafter, the vent assembly 80, in addition to permitting one to control the flow of blood into the flashpoint cavity 76, also permits one to operably connect auxiliary equipment, such as the blood sampling device 24 (see Fig. 7) to the stylete assembly 32, and thus the catheter 22 without leakage of blood therethrough.

Referring more specifically to FIGS. 5-7, the vent assembly 80 and its interconnection with the flashpoint cavity 76 of the observation chamber 74 is illustrated. In order to accomplish the before-mentioned dual function, the vent assembly 80 comprises an air-permeable, liquid-impermeable frit member 82 supported on a distal end 84 of the observation chamber 74. The distal end portion 84 of the observation chamber 74 comprises an externally threaded post member 86 adapted to matingly engage a female member 88 having internally disposed threads 90 of an auxiliary piece of equipment, such as the blood sampling device 24. The threaded post member 86 is provided with a centrally disposed bore 92 extending therethrough, the bore 92 adapted to receive a vent stylet 94 such that one end 96 of the vent stylet 94 extends inwardly into the observation chamber 74 and an opposed second or distal end 98 thereof extends outwardly from the threaded post member 86 of the observation chamber 74. Thus, the vent stylet 94 openly communicates with the flashpoint cavity 76 defined by the observation chamber 74 via a fluid-flow passage bore 99 of the vent stylet 94.

The vent assembly 80 further comprises a fluid-impermeable elastomeric cover member 100 supported by the frit member 82 such that a fluid-tight seal is formed therebetween. The cover member 100 is a tubular member and is positionable over the vent stylet 94 substantially shown. Thus, the cover member 100 is characterzed as having an open first end portion 102 and a closed second end portion 104. In order to secure the cover member 100 to the frit member 82, the first end portion 102 is provided with a skirt 105 adapted to frictionally engage a portion of the frit member 82 such that the fluid-tight seal is formed therebetween. In connecting the elastomeric cover member 100 to the frit member 82, care should be exercised to insure that sufficient surface area of the frit member 82 remains uncovered by the skirt 105 so that air can be expelled from the observation chamber 74 via the vent stylet 94 and the frit member 82 when blood is permitted to flow into the flashpoint cavity 76 of the observation chamber 74. Thus, the frit member 82 cooperates with the vent stylet 94 and the elastomeric cover member 100 so that blood is permitted to flow into the flashpoint cavity 76 of the observation chamber 74 via the skin-penetrating stylet 37 when the skin-penetrating stylet 37 and the catheter 22 are properly positioned within a vein; while preventing the flow of blood from the flashpoint cavity 76 through the vent stylet 94 until such time as auxiliary equipment, such as the blood sampling device 24, has been prop-

erly connected to the threaded post member 86 of the stylet assembly 32.

It should be noted that the cover member 100 is provided with a length such that when the cover member 100 is positioned over the vent stylet 94, the closed second end 104 thereof is disposed substantially adjacent a puncture tip 106 of the vent stylet 94 but in a non-blocking relationship therewith so that fluid flow can be maintained through the fluid-flow passageway 99 of the vent stylet 94. Thus, as blood enters the flashpoint cavity 76 of the observation chamber 74, air is expelled from the flashpoint cavity 76 via the fluid-flow passageway 99 of the vent stylet 94. The air expelled from the vent stylet 94 travels along a passageway 108 formed between the vent stylet 94 and the cover member 100 so as to be directed to the frit member 82 where the air, upon passage therethrough, is discharged to the surrounding environment.

While the cover member 100 has been depicted as being connectable to the frit member 82 via the skirt 105 formed on the first end portion 102 of the cover member 100, any suitable means for connecting the first end portion 102 of the cove member 100 to the frit member 82 so as to form a fluid-tight seal therebetween can be employed. For example, one can employ a suitable adhesive, exercising care to insure that the frit maintains sufficient porosity for the passage of air therethrough, an O-ring, a clamp, or other similar connecting devices.

To prevent exposure of a health care worker to inadvertent puncture by the puncture tip 106 of the vent stylet 94 during placement of the angiocatheter 10 into the vein of a patient, as well as to protect the vent stylet 94 from unnecessary exposure to the environment and potential damage, the vent assembly 80 further comprises a closure member 110 positionable over the vent stylet 94 substantially as shown in FIGS. 1, 2 and 5. The closure member 110 is a cylindrical-shaped member having a first end 112, a closed second end 114 and a cavity 116 openly communicating with the first end 112. To enhance discharge of air from the flashpoint cavity 76 via the vent stylet 94 and the frit member 82, the closure member 110 is desirably provided with at least one air port 117 substantially as shown in FIG. 5. Thus, the closure member 110 can be disposed in a covering position over the vent stylet 94, the elastomeric cover member 100 and the frit member 82 so that the first end 112 supportingly engages the observation chamber 74. Desirably, the closure member 110 frictionally engages the threaded post member 86 so that the cover member 110 is secured in a covering position, while permitting the closure member 110 to be readily removed when access is desired to the vent stylet 94.

When it is determined desirable to attach auxiliary equipment to the angiocatheter 10, such as the blood sampling device 24 (FIG. 7), the closure member 110 is removed so that the vent stylet 94 and the cover member 100 are accessible. The auxiliary equipment, such as the blood sampling device 24, is provided with a throat portion 118 having internally disposed threads 120. When the throat portion 118 is positioned over the vent stylet 94, and the auxiliary equipment is threadably connected to the threaded post member 86 of the observation chamber 74, the throat portion 118 of the device 24 is disposed in a covering position over the frit member 82. Further, when the blood sampling device 24 is threadedly connected to the threaded post member 86, the vent stylet 94 is forced to penetrate the closed second end 104 of the covering member 100 and thereby establish fluid communication with the auxiliary equipment. That is, the blood sampling device 24 compresses the cover member 100 so as to permit penetration of the puncture tip 106 of the vent stylet 94 therethrough, and thereby allows blood to flow from the catheter to the blood sampling device 24.

Because of the elastic properties of the cover member 100, when the blood sampling device 24 is removed from the angiocatheter 10, the cover member 100 returns to its non-compressed condition and once again serves to restrict liquid flow through the vent stylet 94. Further, the elastomeric characteristics of the cover member 100 permit the point of puncture through the closed second 104 thereof to reseal itself so that an effective fluid-impermeable seal is again achieved.

The frit member 82 of the vent assembly 80 is, as previously stated, air-permeable and liquid-impermeable. Thus, the frit member 82 can be fabricated of any suitable material having those 'required properties. For example, the frit member 82 can be fabricated of a ceramic material, non-wicking fibrous material, compressed fibrous polymeric material and the like.

Referring now to FIGS. 8 and 9, the angiocatheter 10 further comprises a retractable sheath 130 connected to and supported by the observation chamber 74 of the stylet assembly 32 so as to minimize exposure of a health care worker to inadvertent puncture by the puncture tip 38 of the skin-penetrating stylet 37 when the skin-penetrating stylet 37 is removed from the passageway 28 of the catheter 22. The retractable sheath 130 comprises an elongated body member 132 having a longitudinally extending passageway 134 adapted to receive the skin-penetrating stylet 37 of the stylet assembly 32; and the retractable sheath 130 is selectively movable between a retracted position (FIG. 8) and an extended position (FIG. 9).

The body member 132 is preferably fabricated of a polymeric material having sufficient rigidity to maintain the body member 132 of the retractable sheath 130 in a substantially rigid, extended position, while at the same time permitting the body member 132 of the retractable sheath 130 to be slidably moved to the ret-

racted position along the skin-penetrating stylet 37 when the skin-penetrating stylet 37 of the stylet assembly 32 is slidably positioned in the fluid-flow passageway 28 of the catheter 22. Further, the polymeric material desirably possesses sufficient memory propercies so that the sheath 130 returns to its extended position when compressive forces maintaining the sheath 130 in its retracted position are removed.

The body member 132 of the retractable sheath 130 is provided with a length greater than the length of the skin-penetrating stylet 37 when same is in the extended position (see FIG. 9) so that the puncture tip 38 of the skin-penetrating stylet 37, as well as the skin-penetrating stylet 37, are completely surrounded by the body member 132 of the retractable sheath 130.

Further to enhance the selective movement of the retractable sheath 130 between the extended position and the retracted position, the body member 132 of the retractable sheath can be provided with a plurality of accordian-like pleats 136 formed along its length. Thus, when the skin-penetrating stylet 37 is positioned within the fluid-flow passageway 28 of the catheter 22, the gasket member 30 exerts a force on an adjacently disposed end 138 of the body member 132 and continued movement of the skin- penetrating stylet 37 through the passageway 28 of the catheter 22 results in compression and folding of the accordian-like pleats 136 substantially as shown in FIG. 8.

When it is determined desirable to remove the stylet assembly 32 from the catheter 22, the reduced force applied to the stylet assembly 32 during withdrawal relaxes or releases the compressive tension on the adjacently disposed end 138 of the body member 130 caused by the gasket member 30 so that the body member 132 of the sheath 130 is allowed to return to its extended position as the skin-penetrating stylet 37 is withdrawn from the fluid-flow passageway 28 of the catheter 22. When the skin-penetrating stylet 37 has been completely withdrawn from the fluid-flow passageway 28 of the catheter 22, the body member 132 of the sheath 130 is positioned in its covering position relative to the skin-penetrating stylet 37 substantially as shown in FIG. 9.

While the sheath 130 has been depicted as an elongated body member having accordian-like pleats formed along its length, it should be understood that any other suitable means can be employed for providing a protective cover for the skin-penetrating stylet 37 when same is removed from the fluid passageway 28 of the catheter 22, such as a telescoping sheath and the like. For example, in FIG. 10 the sheath 130 is illustrated as having a compression spring 140 embedded within the body member 132 so as to enhance the movement of the body member 132 to its extended stylet covering position (FIG. 9) when the skin-penetrating stylet 37 is removed from the fluid passageway 28 of the catheter 22.

From the foregoing description, it becomes apparent that the closed system angiocatheter 10 of the present invention represents an advancement in the state of the art for numerous reasons, including, but not limited to:

(1) providing a barrier for patients from air, germs, viruses and the like during intravenous catheter set-up and use;

(2) providing a barrier to health care workers from potentially infectious blood associated with intravenous catheter use;

(3) minimizes and reduces the number of times a patient has to be stuck with a stylet or needle;

(4) minimizes potential contact with blood and/or blood products by the health care worker during intravenous setup and transfer or intravenous removal; and

(5) minimizes potential contact with an unprotected, potentially contaminated sharp puncture tip of a skin- penetrating stylet after skin-entry by health care workers upon removal of the skin-penetrating stylet from the implanted catheter.

It will be clear that the present invention is well adapted to carry out the objects and attain the advantages mentioned as well as those inherent therein. While a presently preferred embodiment of the invention has been described for purposes of this disclosure, numerous changes can be made which will readily suggest themselves to those skilled in the art and which are encompassed within the spirit of the invention disclosed and as defined in the appended claims.

Claims

1. An improved closed system intravenous catheter positionable within a vein via a puncture site formed by a puncture tip of a-skin-penetrating stylet, the improved closed system catheter comprising:

   a tapered body member having a proximal end portion and a distal end portion, the proximal end portion adapted to be inserted in the vein, the tapered body member having a fluid-flow bore extending therethrough;

   a hub defining a cavity therein, the hub connected to the distal end portion of the tapered body member such that the cavity therein fluidly communicates with the fluid-flow bore of the tapered body member; and

   resilient gasket means supported within the cavity of the hub for sealing the cavity of the hub and the fluid-flow bore of the tapered body member from the atmosphere.

2. The improved closed system catheter of claim 1 wherein the skin-penetrating stylet having the

puncture tip formed at its proximal end is adapted to penetrate the resilient gasket means and extend through the fluid-flow bore of the tapered body member such that the puncture tip of the stylet extends from the proximal end portion of the tapered body member, the gasket means effectively sealing the fluid-flow bore of the tapered body member and the cavity in the hub when the stylet is removed therefrom.

3. The improved closed system catheter of claim 2 wherein the tapered body member and hub are of unitary construction and wherein the resilient gasket means is fabricated of a substantially fluid-impervious elastomeric material.

4. The improved closed system catheter of claim 3 wherein the tapered body member and hub are fabricated of a polymeric material.

5. An improved angiocatheter comprising:

a catheter having a tapered proximal end portion and a hub portion, the catheter having a fluid-flow passageway extending therethrough;

gasket means disposed within the hub portion of the catheter for sealing off the fluid-flow passageway from the outside environment; and

a skin-penetrating stylet positionable within the fluid- flow passageway of the catheter and having a puncture tip at its proximal end for puncturing a puncture site in a patient's skin and for permitting insertion of the tapered proximal end portion of the catheter in a vein, the skin-penetrating stylet disposed within the fluid-flow passageway of the catheter so as to extend through the gasket means such that the puncture tip thereof extends outwardly from the tapered proximal end portion of the catheter, the skin-penetrating stylet alidably disposed in the fluid-flow passageway of the catheter and removable therefrom after proper placement of the catheter into the vein, the gasket means closing off the entry port made by the skin-penetrating stylet so as to seal the fluid-flow passageway of the catheter.

6. The improved angiocatheter of claim 5 wherein the skin- penetrating stylet is further characterized as having a distal end and a fluid-flow bore extending between the puncture tip and the distal end thereof, and wherein the skin-penetrating stylet further comprises:

an observation chamber defining a flashpoint cavity therein, the observation chamber having a first end and an opposed second end, the first end of the observation chamber connected to the distal end of the skin-penetrating stylet such that a fluid-tight seal is formed therebetween and fluid communication is provided between the fluid-flow bore of the skin-penetrating stylet and the flashpoint cavity; and

vent means supported by the opposed second end of the observation chamber for controlling blood flow into the flashpoint cavity when the skin-penetrating stylet is disposed within the catheter and the catheter is positioned in the vein.

7. The improved angiocatheter of claim 6 wherein the vent means comprises:

a vent stylet having a first end portion and an opposed second end portion, the vent stylet connected to the observation chamber such that the first end thereof extends into the flashpoint cavity of the observation chamber and the opposed second end extends outwardly from the observation chamber;

an air-permeable, liquid-impermeable frit supported by the opposed second end of the observation chamber so as to be disposed about an adjacently disposed portion of the vent stylet; and

elastomeric cover means supported by the frit for enclosing the opposed second end portion of the vent stylet and forming a fluid-tight seal therebetween.

8. The improved angiocatheter of claim 7 wherein the distal end of the vent stylet is provided with a puncture tip and wherein the cover means is a substantially air-impervious elastomeric member having a closed second end disposed substantially adjacent the puncture tip of the vent stylet, the closed second end thereof penetrable by the puncture tip of the vent stylet when the elastomeric member is compressed, the elastomeric member effectively sealing the vent stylet when the elastomeric member returns to a non-compressed condition, and wherein the angiocatheter further comprises connector means supported on the opposed second end of the observation chamber for connecting auxiliary equipment to the angiocatheter.

9. The improved angiocatheter of claim 8 further comprising vent capping means disposable peripherially over the vent stylet and the elastomeric member for protecting health care workers from inadvertent contact with the vent stylet and for protecting the vent stylet from damage.

10. The improved angiocatheter of claim 5 wherein the catheter and the observation chamber of the skin-penetrating stylet are fabricated of a polymeric material.

11. The improved angiocatheter of claim 8 further

comprising:

sheath means positionable over the skin-penetrating stylet for selectively covering the skin-penetrating stylet and puncture tip thereof when the skinpenetrating stylet is withdrawn from the fluid-flow passageway of the catheter.

12. The improved angiocatheter of claim 11 wherein the sheath means is connected to the observation chamber so as to extend along the skin-penetrating stylet, the sheath means selectively movable between an extended position and a retracted position, in the extended position the sheath means having a length greater than the length of the skin-penetrating stylet so that the skin-penetrating stylet and puncture tip thereof is substantially covered by the sheath means, in the retracted position the sheath means abuttingly engages the gasket member of the catheter such that the skin-penetrating stylet is positionable throughout the fluid-flow passageway of the catheter and the puncture tip of the skin-penetrating stylet extends outwardly from the tapered proximal end of the catheter.

13. The improved angiocatheter of claim 5 further comprising:

sheath means positionable over the skin-penetrating stylet for selectively covering the skin-penetrating stylet and puncture tip thereof when the skinpenetrating stylet is withdrawn from the fluid-flow passageway of the catheter.

14. The improved angiocatheter of claim 13 wherein the sheath means is connected to the observation chamber so as to extend along the skin-penetrating stylet, the sheath means selectively movable between an extended position and a retracted position, in the extended position the sheath means having a length greater than the length of the skin-penetrating stylet so that the skin-penetrating stylet and puncture tip thereof is substantially covered by the sheath means, in the retracted position the sheath means abuttingly engages the gasket member of the catheter such that the skin-penetrating stylet is positionable throughout the fluid-flow passageway of the catheter and the puncture tip of the skin-penetrating stylet extends outwardly from the proximal end of the catheter.

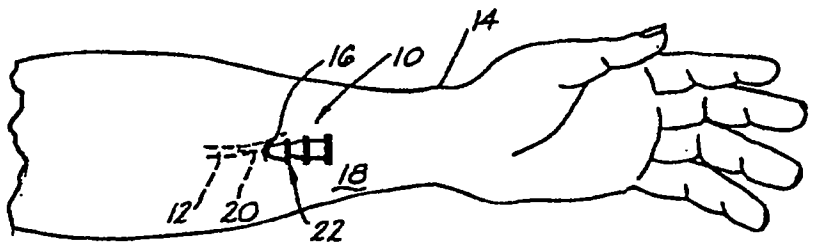

Fig. 1

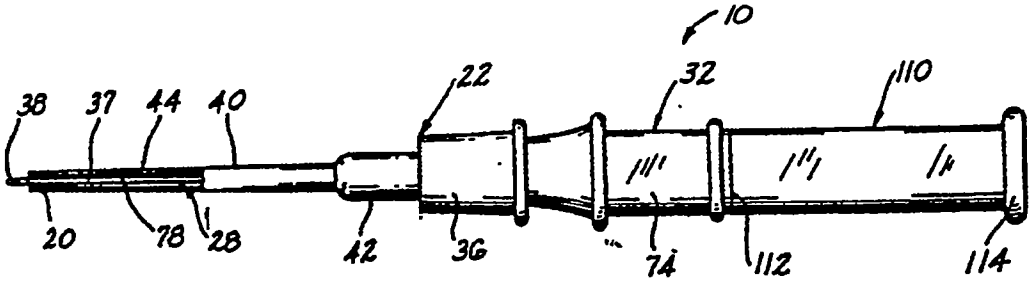

Fig. 2

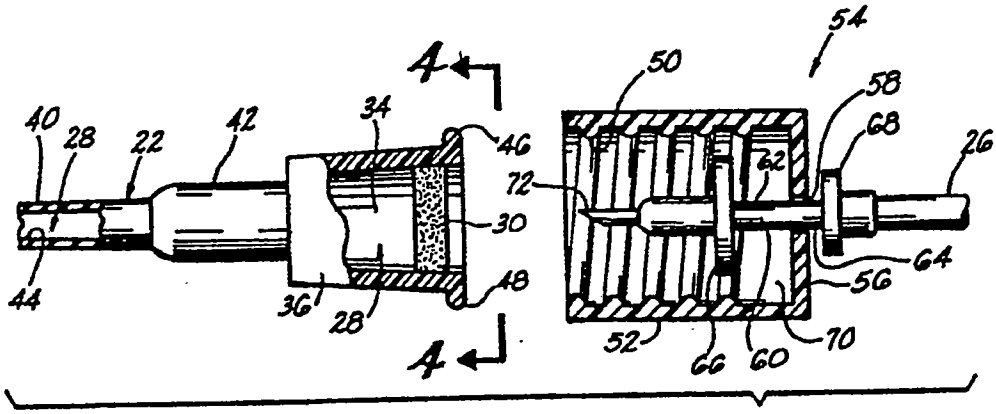

Fig. 3

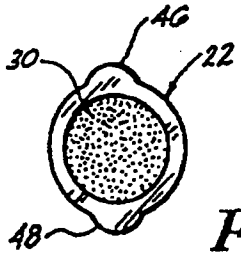

Fig. 4

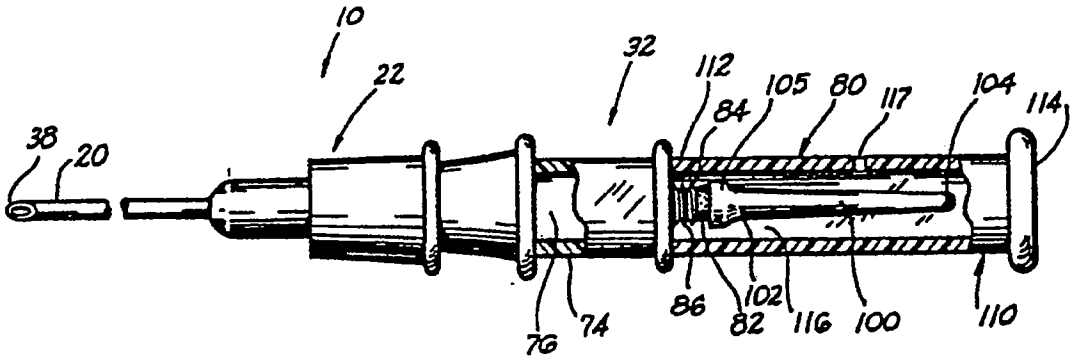

Fig. 5

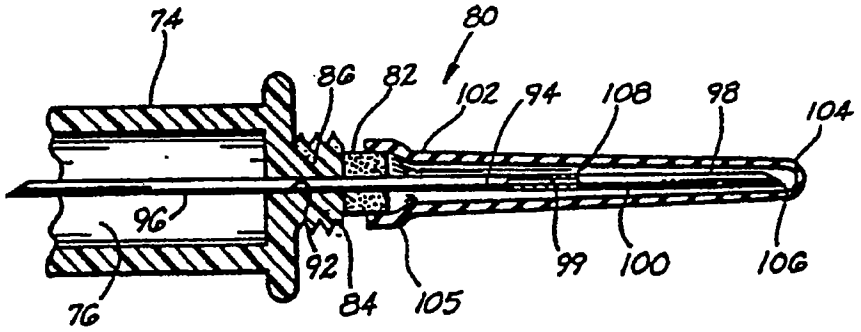

Fig. 6

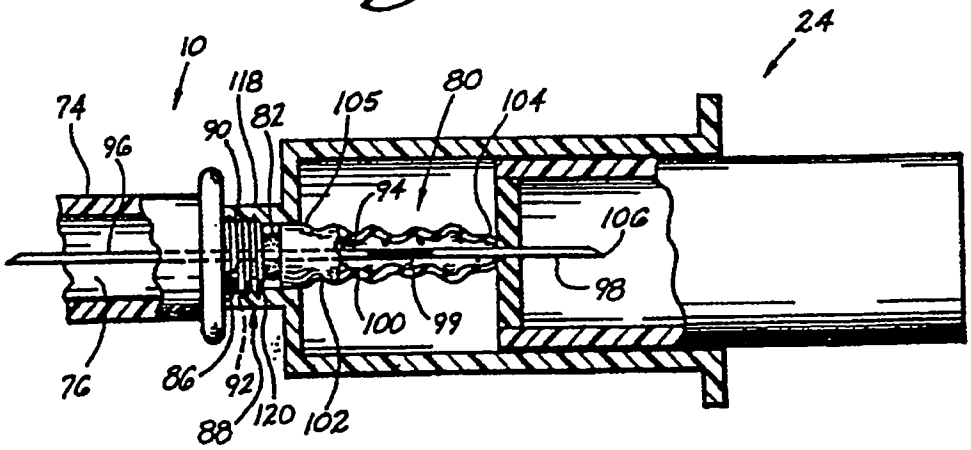

Fig. 7

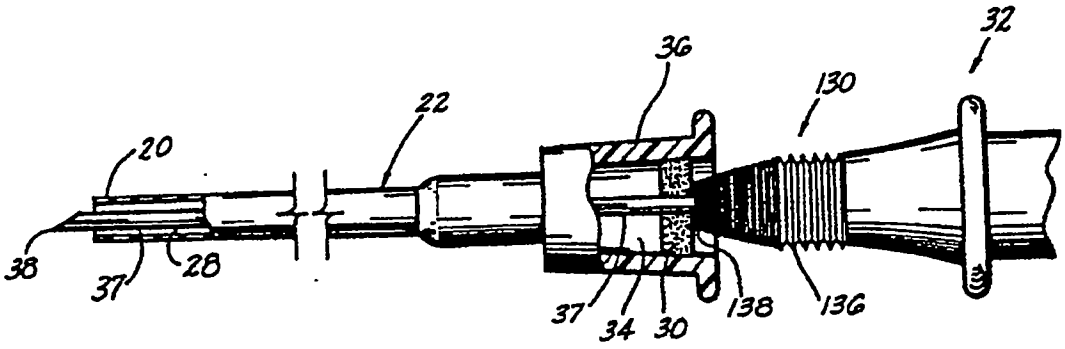

Fig. 8

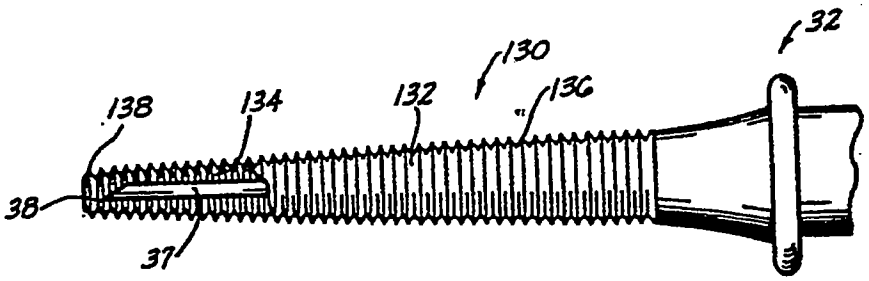

Fig. 9

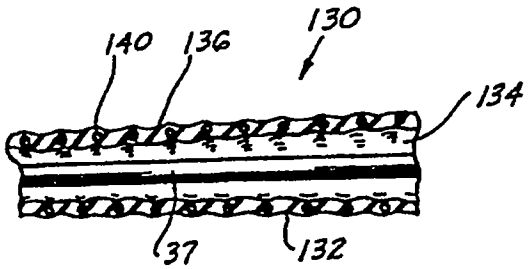

Fig. 10

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 40 0879

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	US-A-4512766 (VAILANCOURT) * column 2, line 41 - column 3, line 14; claims 1, 2; figures 1, 2 *	1-6, 10	A61M25/00 A61M39/00
A		7, 8	
Y	EP-A-0353905 (CRITIKON, INC.) * page 1, lines 1 - 16 * * page 3, lines 15 - 38 * * page 4, line 28 - page 36; figure 2 *	1-8, 10-14	
Y,P	EP-A-0415653 (H.G.WALLACE,LTD.) * column 2, line 34 - column 3, line 10 * * column 4, lines 27 - 35; claims 1, 3; figure 1 *	1-8, 10-14	
Y	DE-A-3210964 (WOLF) * pages 4 - 5, line 23; figures 1, 2 *	5-8	
Y	WO-A-8702254 (PHYSIONIC GESELLSCHAFT FUR MEDIZIN- UND SYSTEMTECHNIK GMBH) * page 1, lines 5 - 10; figures 1-3 *	10-14	
A	US-A-3865236 (RYCROFT) * abstract; figure 1 *	5, 9	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	26 JULY 1991	MICHELS N.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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(54) Device for subcutaneous medication delivery.

(57) Disclosed is an injection port assembly for subcutaneous delivery of medication. A single moulded body (11) has a soft flexible cannula (14) extending downwardly from a generally flat bottom surface and a self-sealing septum (22) mounted at the centre of a top surface which is generally of a concave shape sloping downward towards its outer perimeter at which point the single body is very thin. The single body (11) also has a tubular extension (12) which is directed outward parallel to the skin's surface. A metal needle (8) which penetrates through the septum and through the lumen of the soft cannula is used for inserting the cannula through the skin. The distal section of the needle has an external shoulder which engages an internal shoulder in the cannula so that the cannula will be in tension during insertion thereby preventing an accordion-like compressional failure of the cannula. A quick-release connector on the proximal end of the tubular extension or mounted directly on the injection port assembly allows the tubing connecting the injection port assembly to a portable medication pump to be disconnected when the patient showers or performs some similar activity.

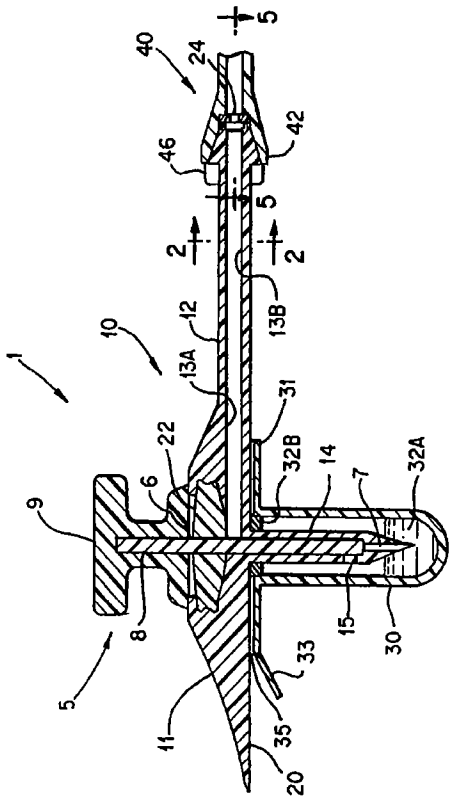

FIG. 1

EP 0 615 768 A2

This invention relates to devices for the subcutaneous delivery of medication, more especially subcutaneous injection ports which are inserted through the skin, and which remain in place for several days to facilitate the periodic or continuous administration of medication.

Currently a major application of such injection ports is to provide chronic delivery of medication such as insulin from portable pumps. When used with a pump, a fluid line is required to connect the injection port to the portable pump. Another application of a subcutaneous injection port is to permit multiple injections without the need to repuncture the skin. In this application, medication is injected from a standard hypodermic syringe and needle through a soft elastomer septum into the injection port which delivers the medication subcutaneously.

If a hollow metal needle is left in place through the skin to provide medication delivery, after one or two days the needle becomes uncomfortable to the patient. To solve this problem, a disposable injection port was described in U.S. Patent No. 3,547,119 by Hall et al which has a soft, thin-walled cannula which is subcutaneously inserted over a metal needle. After insertion, the metal needle is removed leaving only the soft cannula through the skin. However the Hall invention has several limitations, namely:

(1) it is designed for infusion into the bladder and not for subcutaneous injection;

(2) the soft, thin-walled cannula which is subcutaneously inserted over the metal needle is placed in compression during insertion which can result in buckling of the cannula;

(3) the device has an extremely high profile making it impractical for ambulatory use where it is highly desirable to be hidden under clothing; and

(4) it does not provide a bacterial filter.

More recently, a soft cannula subcutaneous injection set described in U.S. Patent No. 4,755,173 by Kanopka et al has become available. While being lower in profile than the Hall device and specifically designed for subcutaneous delivery of medication, the Kanopka invention also has several shortcomings, namely:

(1) there is no method for disconnecting the tubing near the point of subcutaneous insertion, thus requiring a long length of tubing to remain connected while showering, exercising or performing other activities for which having a long length of tubing is disadvantageous;

(2) many separate parts are required to construct the injection set which increases costs and the probability of leakage;

(3) like the Hall device, the soft, thin-walled cannula which is subcutaneously inserted over a hollow needle is placed in compression during insertion which can result in buckling of the cannula;

(4) the multiple parts design results in a comparatively high outward protrusion from the skin;

(5) there is a fluid chamber within the device which is a dead space for medication; and

(6) the cylindrical segment of the catheter hub which extends below the holding pad presses on the skin and often becomes uncomfortable for the patient.

Another soft cannula subcutaneous injection port is described in U.S. patent 4,531,937 by Yates. The Yates device, however, has several disadvantages, namely:

(1) it requires a fluid trapping capability in the needle hub for the expulsion of air from the inside of the device;

(2) like the inventions by Hall and Kanopka, the soft, thin-walled cannula which is subcutaneously inserted over a hollow needle is placed in compression during insertion which can result in buckling of the cannula;

(3) it has a "stepped bore" diameter which forms a fluid chamber within the device which is a dead space for medication;

(4) it does not provide a bacterial filter; and

(5) it lacks a flat surface for attachment to the skin to prevent bending of the soft cannula during prolonged insertion.

Still another soft cannula injection port is described in U.S. patent 4,311,137 by Gerard. The Gerard device, however, has several disadvantages, namely:

(1) it requires a complex movable needle/septum assembly with one position for flushing and a second position for insertion;

(2) it has a lumen (referred to as a passage) which forms a fluid chamber within the device which is a dead space for medication;

(3) it does not provide a bacterial filter;

(4) the Gerard design results in a comparatively high outward protrusion from the skin; and

(5) like the inventions by Hall, Kanopka, and Yates, the soft, thin-walled cannula which is subcutaneously inserted over a hollow needle is placed in compression during insertion which can result in buckling of the cannula.

In a primary aspect of the present invention there is provided a subcutaneous injection and medicament delivery system which facilitates the placement of a flexible cannula in the subcutaneous tissue and which improves patient comfort and convenience. To this end there is provided a subcutaneous injection system for the periodic or long term delivery of a medicament subcutaneously to a patient, said system comprising:

a generally flat, moulded plastics body portion having a generally planar undersurface which is shaped to engage against the surface of the skin in surrounding relationship to the site of delivery of the medicament to the patient;

a flexible cannula projecting downwardly from the underside of the moulded body portion, said can-

nula having a central lumen which communicates with a passageway formed in said body for the through-flow of medicament from an inlet port in the moulded body to the cannula, and through the lumen of the cannula to a delivery port formed in the distal end of the cannula; and

a stylet needle removably insertable into the cannula through the moulded body, said needle having a length greater than that of the cannula so that, when inserted therein, the tip of the needle projects beyond the distal end of the cannula,

said needle having adjacent its tip an outwardly projecting shoulder which, when the needle is inserted into the flexible cannula, engages against an inwardly projecting shoulder formed in the lumen of the cannula adjacent its distal end, so that engagement of the needle into the cannula serves to tension the flexible cannula and prevent the cannula from buckling as the needle and cannula are pushed through the patient's skin, the needle thereafter being withdrawn to leave the cannula in place and with the undersurface of the moulded body portion lying against the patient's skin.

In another aspect, the present invention seeks to overcome other deficiencies of these prior art devices by providing a subcutaneous injection port which includes a quick-release connector which would typically be placed 5 to 10 cm from the device's main body. In another embodiment, the quick-release connector is placed directly onto the main body. Thus the soft cannula could remain in place through the skin while virtually all of the 100 plus cm of tubing connected to the portable pump could be temporarily detached and placed on a clean surface. When the main tubing is detached, a disposable sterilised cap can be placed over the quick-release connector to keep it sterile while showering, exercising or performing any other activity for which it is desirable to remove the long length of tubing. Furthermore, the connector can have a hard plastic needle which can penetrate through a previously slit septum on the injection port to provide a fluid path from an external portable pump, through the injection port and subcutaneously into the patient.

According to another aspect of the present invention, an in-line bacterial filter is incorporated into the subcutaneous injection port so that when the connecting tubing is removed, a cap is not needed to prevent bacteria from entering the injection port. Such an in-line bacterial filter will, when dry, allow venting of air from the device and when wet (after priming) prohibit air bubbles from passing into the body. This is of particular importance for intravenous use.

Another aspect of the present invention resides in a soft elastomer septum for hypodermic needle injection of medication via the device. This septum may be directly incorporated into the main body of the injection port or it can be contained in a quick-release connector which mates with the quick-release connector on the injection port.

Another important aspect of the present invention is a one piece main body design which replaces five separate pieces and does not include a cylindrical segment extending below the bottom surface of the holding pad as required for the Kanopka et al invention. The one piece design reduces costs and further reduces the probability of a fluid leakage. The one piece design and the absence of a fluid chamber decreases the height of the device above the skin resulting in a desirable low profile which is more easily hidden under clothing. Another feature of the present invention is to allow the placement of a soft cannula at angles between 20 and 80 degrees relative to the bottom surface of the injection port which could be advantageous for intravenous insertion.

Another aspect of the present invention resides in a needle guard which is removed prior to placing the needle and cannula through the skin and which can contain a broad spectrum antibiotic substance such as an antibiotic ointment. Thus, when the needle guard is removed, some ointment remains on the needle which ointment can decrease infections at the insertion site and also can act as a lubricant for the exterior surface of the cannula.

Still another feature of the cannula is that it can be made with a side port which can allow continued delivery of medication even if the end port becomes blocked. Also, the side port allows for more diffuse infusion of the medication so that it would be taken up more quickly into the body.

Still another feature of the present invention is a concave upper surface of the single body which results in a flexible edge at the outside diameter of the main body. This is more comfortable for the patient because the flexible edge will more readily adapt to the changing shape of the skin surface.

These and other important features of this invention in all its varius independent aspects, as defined in the claims, will become apparent from the following detailed description of the invention made with reference to the accompanying drawings in which

Figure 1 is a longitudinal cross section of the device shown in its form prior to insertion through the skin.

Figure 2 is a transverse cross section of the device at section 2-2 of Figure 1.

Figure 3 shows the bottom of the device with the needle guard removed.

Figure 4 is a longitudinal cross section of the injection port and body tubular extension showing how the soft, flexible cannula is subcutaneously inserted into the subcutaneous fat.

FIG. 5 shows an enlarged cross section of the quick-release connector at section 5-5 ofFIG. 1.

FIG. 6 shows an end cap.

FIG. 7 is a longitudinal cross section of an alter-

nate embodiment of the device shown in its form prior to insertion through the skin which embodiment shows a bacterial filter, a mini-Luer lock fitting for quick-release, a hollow upper tube insertion needle and a soft elastomer septum at the proximal end of the quick-release fitting for hypodermic injection of medication via the device.

FIG. 8 is a longitudinal cross section of still another embodiment of the device shown in its form prior to insertion through the skin. This embodiment contains a bacterial filter, and both a means for hypodermic injection as well as delivery of medication from an external, portable pump.

FIG. 9 is a longitudinal cross section of yet another embodiment of the device shown in its form prior to insertion through the skin. This embodiment contains a bacterial filter, and only a means for hypodermic injection of medication.

FIG. 10 is a top plan view of another embodiment of an injection port.

FIG. 11 is a cross section at 11- 11 of the embodiment of the injection port shown in FIG. 10.

FIG. 12 is a cross section at 12-12 of the embodiment of the injection port shown in FIG. 10.

FIG. 13 is a top plan view showing a three-pronged connector mounted at the center of the injection port.

FIG. 14 is a side view of the connector and injection port.

FIG. 15 is a cross section of the three-pronged connector and the injection port showing the needle assembly removed and the three-pronged connector above the top surface of the injection port.

FIG. 16 is a cross section of the three-pronged connector shown attached to the injection port.

FIG. 17 is a cross section of the needle assembly and injection port showing the needle assembly as it is used to place the cannula through the skin and into the subcutaneous fat.

FIG. 18 is a cross section of a needle assembly that automatically shields the needle point with the needle shown in its retracted position.

Figure 19 is a cross section of a needle assembly that automatically shields the needle point with the needle shown in its extended position for inserting the injection port cannula through the skin.

Referring now to the drawings, Figure 1 shows a cross-sectional view of a system according to the invention as it would appear immediately prior to insertion through the skin. The medication injection port system 1 consists of five subassemblies, namely: the insertion needle assembly 5, the injection port assembly 10, the needle guard 30, the quick-release connector assembly 40 and the cap assembly 50 (shown in Figure 6). The needle assembly 5 consists of a solid core needle 6 having a proximal section 8 and a reduced diameter distal section 7 and a rigid plastic handle 9. The needle 6 could also be entirely or partially hollow and would typically be made from a stainless steel such as type 304. The diameter of the needle would typically be 0.45 mm except for the distal section 7 which would typically be 0.25 mm.

The injection port assembly 10 consists of a one piece main body 11 having a tubular body extension 12, an inlet lumen 13A, a tubular lumen 13B and a soft, flexible cannula 14 having a side port 15. Although it is ideal to have the body extension 12 and the soft cannula 14 moulded into the main body 11, the present invention also envisions either one of these two parts to be formed separately and then bonded or adhesively joined into the main body 11. A removable needle guard 30 which is temporarily attached to the bottom surface 20 of the main body 11 protects the patient from being inadvertently stuck by the needle's sharp end prior to insertion through the skin. The needle guard 30 is shown with a thin, flexible flange 31 that has a tab 33 which extends beyond the perimeter of the flange 31 at one place on the flange's perimeter. A pressure sensitive adhesive coating 35 placed on the upper surface of the flange 31 holds onto the bottom surface 20 until the tab 33 is used to pull the flange 31 and needle guard 30 away from the main body 11. It is also envisioned that the adhesive could be placed on the bottom surface 20 of the body 11 where it would adhere to the skin after the needle guard is removed.

Within the needle guard 30 there can be placed an antibiotic ointment either at site 32B if it is desired that the ointment only cover the insertion puncture wound after insertion, or the ointment can be placed at position 32A it if is also desired to lubricate and coat the exterior surface of the cannula as it is inserted through the subcutaneous tissue. It should be noted that there is a closed, air tight volume within the needle guard 30 that would prevent drying out of an antibiotic ointment prior to the needle guard's removal from the bottom surface of the main body 11. It should also be noted that the shipping package which is used to sterilise and ship the injection port assembly could also have moulded into it a needle guard section which could also include an antibiotic ointment. Preferably the undersurface of the body 11 is provided with a groove (not shown) surrounding the cannula, so that as the needle and cannula are pushed through the skin, excess antibiotic collects in that groove rather than being squeezed out between the skin and the undersurface of the body portion 11.

Also shown in Figure 1 is a self-sealing, soft, elastomer septum 22 which seals the fluid lines after the needle 6 is pulled out. The septum 22 would typically be fabricated from a low durometer silicone rubber that has been placed in compression.

Figure 2 shows the transverse cross-section of the tubular body extension 12 which encloses the lumen 13B. The connector housing 42 and quick-release actuator buttons 46 are shown in Figures 1

and 2. The tubular extension 12 terminates in a quick-release connector 40 which is also illustrated in Figure 5. Figures 1 and 5 show a soft elastomer seal 24 within the quick-release connector 40 which provides a fluid tight seal.

Before insertion of the injection port system 1 into the skin, the guard 30 is removed. When this is accomplished, the view of the bottom of the injection port assembly 10 would be as shown in Figure 3. After the guard 30 is removed, the user would grip the needle assembly handle 9 and push it and the soft cannula 14 through the skin. When doing this, the exterior shoulder of the needle (where proximal section 8 joins distal section 7) cooperates with an interior shoulder in the cannula 14 to place most of the length of the cannula 14 in tension. This design prevents the soft, flexible cannula 14 from folding up like an accordion (i.e. buckling) when it is pushed through the skin.

Figure 4 shows the injection port assembly 10 with the needle assembly 5 removed and the soft cannula 14 in place with its distal end lying in the subcutaneous fat. Also shown in Figure 4 is the quick-release connector 40 whose female connector is joined to the distal end of the tubing 60 and whose proximal end is connected to a portable pump (not shown). Thus the liquid medication coming out of the pump first passes through the lumen 62 of the tubing 60, then the lumen 13B of the tubular body extension 12, then through the inlet lumen 13A of the main body 11, then through the exit lumen 18 of the flexible cannula 14 and finally out the end hole 19 of the cannula 14 and/or through the cannula's side port 15. It should be understood that the side port 15 could be omitted. Conversely, the end hole 19 could be replaced by a sharpened point and only the side hole(s) 15 could be used. Also, the tubular body extension 12 could be formed from a separate piece of plastic and then joined with a fluid tight seal into the body 11. It should be noted that there is an absolutely no fluid chamber within the main body 11. This is a result of the bottom surface of the septum 22 being placed at the proximal end of the exit lumen 18. There are only the continuous lumens 13A, 13B and 18 through which the medication flows. Therefore there is not the disadvantage of having a fluid chamber dead space which increases the height of the main body and in which medication such as insulin could precipitate out as solid insulin. In this embodiment, the lumens 13A and 13B are the connecting lumens between the quick-release connector assembly 40 and the exit lumen 18 in the soft cannula 14.

It should be noted that the upper surface of the main body 14 is concave. This shape maximizes the flexibility of the outer perimeter of the main body 11. This provides for more patient comfort because where the main body perimeter joins onto the skin, it will more readily follow a changing shape of the skin surface. FIG. 4 also shows an adhesive tape 29 which extends for approximately 6 mm beyond the outer perimeter of the main body 11. This tape would also follow the skin's changing shape. The FIG. 4 embodiment does not use an adhesive on the bottom surface of the main body 11, however such an adhesive could be used instead of or in combination with the adhesive tape 29 to hold the main body 11 against the patient's skin.

FIG. 4 also shows a flat surface on the bottom of the main body 11. This is in contradistinction to the Yates invention which shows no flat surface at all and the Kanopka et al invention which requires a cylindrical segment extending below the bottom surface of a holding pad into which cylindrical segment the soft cannula is inserted. Although there may be some advantages to a cylindrical segment extending below the bottom surface of Kanopka's "holding pad", such a cylindrical segment protruding into the skin for several days can be uncomfortable for some patients. The flat surface at the bottom of the main body 11 should be more comfortable for long term use for most patients.

FIG. 5 shows a view of the quick-release connector assembly 40 which is orthogonal to the views shown in FIGS. 1 and 4. The tubular extension 12 has at its proximal end a tapered male portion in the form of a flat top pyramid with two broad sides and two narrow sides. The broad sides lie generally parallel to the skin while the two narrow sides are perpendicular to the skin surface. This is also true for the tubular extension 12 whose broad surfaces lie parallel to the skin and whose narrow surfaces lie perpendicular to the skin. This geometry makes it easy for the patient to bend the tubular extension upward away from the skin in order to easily squeeze the actuator buttons 46 of the quick-release connector 40. This geometry also places the quick-release actuator buttons 46 in an orientation where they cannot be inadvertently released by pushing down on the skin at the site of the quick-release connector. It should be understood that a cylindrical tubular extension would also be satisfactory.

Returning now to FIG. 5 we see that the male portion has a taper 41A which mates with the taper 41B of the female portion of the quick-release connector 40. Each actuator button 46 is mounted on a flexure 47 which also has the male detent 43 mounted on its exterior surface. When the female detent 44 is mated with the male detent 43, the quick-release connector 40 has its two portions firmly joined together with the circular ridge 49 making a fluid tight juncture with the elastomer washer 24. When the index finger and thumb are placed on and squeezed together onto the actuator buttons 46, the quick-release connector 40 can be easily separated by pulling outward on the tubing 60. For reconnection, the tubular extension 12 and the tubing 60 are pushed together until the detents 43 and 44 are joined. If the male and female por-

tions of the quick-release connector 40 are rotated by 180 degrees, the male detents 43 will still snap into the female detents 44. Thus, the patient need not be aware of the angular orientation of the tubular extension 12 relative to the tubing 60 other than the fact that the broad sides of the male and female portions must be aligned. Alternatively, a Luer lock fitting, especially a miniature version as shown in FIG. 7, could accomplish the same function as the quick-release connector 40.

When the female portion of the connector 40 and the tubing 60 are disconnected from the male portion, a sterilized disposable female cap 50 shown in FIG. 6 can be placed over the male portion. The female detents 54 would then mate with the male detents 43, and the circular ridge 49 would seal against the soft elastomer seal 57. The handle 58 on the cap 50 makes for easy assembly with the male portion of the quick-release connector 40. If desired, a properly configured male plug (not shown) could be used to close off the female portion of the quick-release connector 40 when the male and female portions are separated. It should be understood that the cap 50 would be used to maintain sterility when showering, swimming or performing any other activity which would be enhanced by disconnecting the tubing 60 and the portable medication pump from the main body assembly 10. To reconnect the pump, the female cap 50 is removed and the quick-release connector 40 is reconnected.

The main body 11 and needle handle 9 would typically be molded from Teflon, Surlyn, polyurethane or any similar plastic which is readily formed by injection molding. The tubing 60 could be formed with an interior cylinder (not shown) of polyolefin or a similar plastic and an outer tubing (not shown) of PVC or a similar plastic. It is important that all surfaces in contact with the medication do not degrade that medication.

It should also be noted that the lengths of the needle 6 (including the distal portion 7) and the cannula 14 could be varied in order to accommodate individuals with different thicknesses of subcutaneous fat. For example, a soft cannula length of 8.5 mm below the bottom surface 20 of the body 11 could be used for most individuals. For pediatric use or for very thin individuals, one-quarter to two-thirds that length would be appropriate. For individuals with a thicker fat layer, or for suprapubic or intravenous use, an increased length of soft cannula could be used.

It is also envisioned to coat the exterior surface of the cannula 14 with a lubricity coating to aid in its insertion through the skin.

In FIG. 7 is shown a cross-sectional view of an alternate embodiment of the present invention as it would appear immediately prior to insertion through the skin. The medication injection port system 100 consists of four subassemblies, namely: the needle guard 51, the insertion needle assembly 80, the injection port assembly 70 and the mini-Luer-lock connector assembly 90. The needle assembly 80 consists of a hollow tube proximal section 86 and a reduced diameter solid needle distal section 88. A proximal portion of the proximal section 86 is fixedly attached to a comparatively rigid plastic handle 82. The tube 86 has an inlet port 84 which allows the passage of fluid from the inlet lumen 13A into the lumen 85 of the tube 86. Fluid entering the lumen 85 will flow out of the top opening of the needle's proximal section 86. This allows the fluid passageways in the injection port system 100 to be flushed out or primed (i.e., have air removed from the lines) either prior to or after subcutaneous insertion of the soft cannula 14. Both the hollow and the solid sections of the needle would typically be made from a stainless steel such as type 304. The outside diameter of the proximal section 86 would typically be 0.45 mm and the diameter of the distal section 88 would typically be 0.25 mm.

The injection port assembly 70 consists of a one piece main body 11 having a (typically) flat tubular body extension 12 with a lumen 13B which is in fluid communication with the inlet lumen 13A and the exit lumen of the soft cannula 14 having a side port 15. Although it is ideal to have the body extension 12 and the soft cannula 14 molded into the main body 11, the present invention also envisions either one of these two parts to be formed separately and then bonded or adhesively joined into the main body 11. A removable needle guard 51 which fits into a groove 16 of the main body 11 protects the patient from being inadvertently stuck by the needle's sharp end prior to insertion through the skin. Within the needle guard 51 there can be placed an antibiotic ointment either at site 53B if it is desired that the ointment only cover the insertion puncture wound after insertion, or the ointment can be placed at position 53A if it is also desired to lubricate and coat the exterior surface of the cannula as it is inserted through the subcutaneous tissue. Also shown in FIG. 7 is a self-sealing, soft, elastomer septum 22 which seals the fluid lines after the insertion needle assembly 80 is pulled out. The septum 22 would typically be fabricated from a low durometer silicone rubber that has been placed in compression.

A bacterial filter 78 is placed in the fluid path within the injection port 70 to prevent the delivery of bacteria into the subcutaneous tissue. Such a bacterial filter 78 is shown as part of the mini-Luer lock fitting 72 attached to the injection port 70. A filter support disk 74 provides structural support for the bacterial filter 78 while allowing free passage of fluid into the lumen 13B.

The mini-Luer lock connector assembly 90 consists of a male miniature Luer lock fitting containing a soft, self-sealing elastomer injection septum 92 through which hypodermic needles can be inserted to inject medication from a syringe. A needle stop 94 with holes too small in diameter for a needle to pene-

trate prevents the hypodermic needle from damaging the bacterial filter 78. Because of the needle stop 94, fluid from a hypodermic needle syringe will be injected into the lumen 96, pass through the needle stop 94 then through the bacterial filter 78 into the main body of the injection port 70. The injection septum 92 would typically be fabricated from a low durometer silicone rubber that has been placed in compression. The connector assembly 90 would typically be located between 5 and 10 cm from the needle assembly 80; and would always be less than 25 cm away. Most typically, the connector 90 would be located at a position from the edge of the main body 11 within a distance that is less than the diameter of the main body 11.

Although FIG. 7 shows an injection septum 92 at the end of the mini-Luer lock assembly 90, it is understood that, as in FIG. 1, this connector could instead attach to a length of flexible tubing for connection to an external, portable medication pump.

In FIG. 8 is shown a cross-sectional view of still another embodiment of the present invention as it would appear immediately prior to insertion through the skin. The medication injection port system 110 consists of four subassemblies, namely: the insertion needle assembly 80, the needle guard 114, the injection port assembly 120 and the mini-Luer-lock connector assembly 130. The needle assembly 80 consists of a hollow tube 86 having a reduced diameter solid needle 88 inserted into its distal end and a comparatively rigid plastic handle 82. The tube 86 has an inlet port 84 which allows the passage of fluid from the lumen 113 into the lumen 85 of the tube 86. Fluid entering the lumen 85 will flow out of the top of the tube 86. This allows the fluid passageways in the injection port system 110 to be flushed out or primed; i.e., medication displaces the air in the fluid lines. The tube 86 and solid needle 88 would typically be made from a stainless steel such as type 304. The outer diameter of the tube 86 would typically be 0.45 mm and the diameter of the needle 88 would typically be 0.25 cm.

The injection port assembly 120 consists of a one piece main body 111 having a flat tubular body extension 115 with a lumen 113 and a soft, flexible cannula 14 having a side port 15. Although it is ideal to have the body extension 115 and the soft cannula 14 molded into the main body 111, this and other embodiments envision either one of these two parts to be formed separately and then bonded or adhesively joined into the main body 111. A removable needle guard 114 which fits into a groove 116 of the main body 111 protects the patient from being inadvertently stuck by the needle's sharp end prior to insertion through the skin. Also shown in FIG. 8 is a self-sealing, soft, elastomer septum 122 which is placed in compression by a septum cap 123. The septum 122 seals the fluid lines after the insertion needle assembly 80 is pulled out. The septum 122 would typically be fabricated from a low durometer silicone rubber that has been placed in compression. Above the septum 122 is an injection hole 124 in the septum cap 123. Below the septum 122 and in line with the injection hole 124, is an injection chamber 126 which is in fluid communication with the bacterial filter chamber 112 on one side and the lumen 113 on the other. After subcutaneous insertion and then removal of the needle assembly 80, the bacterial filter chamber 112 connects through the main body connecting lumen 118 to the exit lumen of the soft cannula 14.

To prevent the delivery of bacteria into the patient's body, a bacterial filter 128 is placed in the fluid path between the injection chamber 126 and the exit lumen of the soft cannula 14 through which medication is delivered into the patient. A filter support disk 129 provides structural support for the bacterial filter 128 while allowing free passage of fluid into the exit lumen of the soft cannula 14. A check valve 121 is located between the mini-Luer lock connector 125 and the injection chamber 126. After subcutaneous insertion of the cannula 14 and removal of the needle assembly 80, medication delivered by a hypodermic syringe through the septum 122 into the injection chamber 126 will flow through the bacterial filter 128 into the connecting lumen 118, through the exit lumen in the soft cannula 14 and into the patient's body because the check valve 121 prevents flow out through the lumen 134.

The mini-Luer lock connector assembly 130 consists of a male miniature Luer lock fitting 131 which connects to a length of flexible tubing 132 with lumen 134 which would connect to an external fluid pumping device. Medication from a pump would flow through the lumen 134 in the flexible tube 132, through the check valve 121 into the lumen 113 in the flat tubular body extension 115 of the one piece main body 111, then through the injection chamber 126 through the bacterial filter 128, filter support disk 129, and lumen 118 into the exit lumen of the soft cannula 14 and then into the patient's body.

In FIG. 9 is shown a cross-sectional view of yet another embodiment of the present invention as it would appear immediately prior to insertion through the skin. The medication injection port system 150 consists of three subassemblies, namely: the insertion needle assembly 80, the needle guard 114 and the injection port assembly 160. The needle assembly 80 consists of a hollow tube 86 having a reduced diameter solid needle 88 inserted into its distal end and a plastic handle 82. The tube 86 has an inlet port 84 which allows the passage of fluid from the lumen 126 into the lumen 85 of the tube 86. Fluid entering the lumen 85 will flow out of the top exit port of the tube 86. This allows the fluid passageways in the injection port system 150 to be flushed or primed.

The injection port assembly 160 consists of a one piece main body 151 having a soft, flexible cannula

14 which has two side ports 15. Although it is ideal to have the soft cannula 14 molded into the main body 151, the present invention also envisions either one of these two parts to be molded separately and then bonded or adhesively joined into the main body 151. A removable needle guard 114 which fits into a groove 116 of the main body 151 protects the patient from being inadvertently stuck by the needle's sharp end prior to insertion through the skin. Also shown in FIG. 9 is a self-sealing, soft, elastomer septum 122 which is placed in compression by a septum cap 123. The septum 122 seals the fluid lines and chambers after the insertion needle assembly 80 is pulled out. The septum 122 would typically be fabricated from a low durometer silicone rubber that has been placed in compression. Above the septum 122 is an injection hole 124 in the septum cap 123. Below the septum 122 and in line with the injection hole 124, is an injection chamber 126 which is in fluid communication with the bacterial filter chamber 112.

A bacterial filter 128 to prevent the delivery of bacteria into the patient's body is placed in the fluid path within the injection port 160 between the injection chamber 126 and the exit lumen of the soft cannula 14 which delivers medication to the patient. A filter support disk 129 provides structural support for the bacterial filter 128 while allowing free passage of fluid into the exit lumen of the soft cannula 14. After subcutaneous insertion of the cannula 14 and removal of the needle assembly 80, medication delivered by a hypodermic syringe through the septum 122 into the injection chamber 126 will flow through the bacterial filter 128 into the connecting lumen 118 and through the exit lumen in the soft cannula 14 and into the patient's body.

Although FIG. 7, 8 and 9 show vertically oriented, disk-shaped bacterial filters, it is understood that the shape of the filter might be cylindrical, or rectangular and the orientation could be at any angle.

Although FIGS. 1, 4, 7, 8 and 9 show a flexible cannula 14 which is generally perpendicular to the bottom surface 17 of the main body, it should be understood that there could be conditions which would require the cannula 14 to be inclined at an angle between 20 and 80 degrees relative to the bottom surface 17. Such angles could be advantageous for intravenous insertion of the cannula 14.

Although FIG. 8 shows a check valve 121 to prevent flow out of the mini-Luer lock connector 130 during hypodermic injection, it is clear that alternate means for preventing such flow such as a closed mini-Luer cap could be used to prevent such flow.

FIGS. 10, 11 and 12 illustrate another embodiment of an injection port assembly 200 which consists of three sub-assemblies, namely: a main body 210, a cannula section 220 and an adhesive assembly 230. The main body 210 is generally in the form of a flat, circular disk. Two projections 201 are aligned in the direction of the guide ridges 202. The interior surface 203 of the guide ridges 202 are used to help guide the plastic needle 245 (shown in FIGS. 15 and 16) into the slit 204 of the septum 205 which is located at the center of the ridges 202 which is also the center of the main body 210. The projections 201 aid the patient in aligning the injection port assembly 200 in a generally horizontal direction when adhesively attaching it to the skin in the abdominal region. When the ridges 202 are in a horizontal position, it is somewhat easier for the patient to slide the plastic needle 245 into its proper place inside the ridges 202 and into the slit 204.

The cannula section 220 is best shown in FIGS. 11 and 12. The cannula section 220 consists of a flexible cannula 221 having a tapered entry section 222 located within a central section 223 that forms a pressure tight seal with the main body 210 just beneath the septum 205. An outer section 224 includes a lip 225 which is designed to engage a mating projection 247 of the three-pronged connector 240 as shown in FIGS. 15 and 16. The cannula section 220 also includes two tapered entry holes 226 which guide the tapered locking pins 246 of FIGS. 15 and 16 into the cannula section 220.

Adhesive assembly 230 consists of a two-sided adhesive sheet 232 which is joined on its inner surface to the underside of the main body 210, and on its outer side to two removable plastic sheets 234 which are separated by a diagonal cut 238 as shown by the dotted line in FIG. 10. When the tabs 236 which are part of the plastic sheets 234 are pulled away from the bottom surface of the main body 210, the outer adhesive surface of the adhesive sheet 232 is exposed and the injection port 200 can then be adhesively joined to the patient's skin, The projections 201 of the main body 210 are useful in pulling the injection port 200 off the skin.

FIGS. 13 and 14 illustrate the connector and tubing assembly 240 which has a three-pronged connector 241 mounted onto the main body 210 of the injection port 200. The assembly 240 consists of the connector 241 which is joined to a fluid connector 242 by means of tubing 243. The fluid connector 242 is typically a female Luer connector that is adapted to join to an external source of medication such as a portable insulin pump (not shown). The three-pronged connector 241 as illustrated in FIGS. 13, 14, 15 and 16 has a central prong 244 that is used to help guide the plastic needle 245 into the slit 204 of the septum 205 of the main body 210. The connector 241 is also guided into the tapered entry holes 226 of the main body 210 by means of the tapered locking pins 246 located on the outer two prongs of the three pronged connector 241. Thus, when the connector 241 is positioned just above the main body 210 as shown in FIG. 15, a downward finger pressure can be used to push the locking pins 246 into the tapered entry holes 226 as shown in FIGS. 15 and 16. When this is accom-

plished, the lip 225 of the cannula section 220 is locked onto the mating lip 247 of the locking pins 246. To remove the connector 241 from the cannula section 220, the patient uses his thumb and forefinger to squeeze together the outer surfaces 248 of the outer prongs of the connector 241. When this is done, the lips 225 and 247 disengage, and the connector 241 can be pulled out of the cannula section 220.

If the connector 241 is placed on a flat surface such as a table after it is pulled out of the cannula section 220, it will be noted that the plastic needle 245 will not touch the table surface. Thus the sterility of the plastic needle 245 can be maintained without placing a special cap over it. Furthermore, the flat upper surface of the septum 205 can be wiped with an alcohol swab before reinserting the plastic needle 245, thus assuring a sterile connection of the three-pronged connector 240 and precluding the need for a special sterility maintaining cover to be placed over the septum 205 when the connector 241 is removed from the cannula section 220. It should also be understood that the priming can be accomplished by attaching the connector 242 to a source of medication and pumping the medication through the tube 243 and then out the central lumen 249 of the plastic needle 245. The connector 241 can then be joined into the cannula section 220.

FIG. 17 illustrates a needle assembly 250 that is used to subcutaneously place the cannula 221 of the injection port 200. The needle assembly 250 consists of pointed needle 251 placed inside the cannula 221. The needle 251 is joined at its proximal end to a hollow handle 252. The shape of the proximal end 253 of the needle handle 252 as shown in FIG. 17 is ideal for secure placement of a finger tip when pushing the needle 251 and cannula 221 through the skin. After this is accomplished, the main body 210 is pushed firmly against the skin thus assuring a good adhesive connection of the injection part 200 onto the skin. The needle assembly 250 is then removed and the connector 241 is inserted into the cannula section 220 as illustrated in FIGS. 13, 14, 15 and 16.

The material of the main body 210 would be a low durometer elastomer such as silicone rubber, polyurethane or polyethylene. The cannula section would be molded from a similar elastomer material but of a considerably higher durometer. The connectors 241 and 242 and the needle handle 252 would be molded from a hard plastic such as polycarbonate. The main body 210 would be between 2 and 5 cm in diameter with all other dimensions being approximately as scaled from the drawings of FIGS. 10 to 17 inclusive.

FIGS. 18 and 19 show another embodiment of a needle assembly 260 that is designed to avoid inadvertent needle sticks by the patient or health care worker who places the injection port assembly onto the patient. The needle assembly 260 consists of a housing 261, slideable needle 262 and a compressional coil spring 263. The housing 261 consists of a body 265, a plastic needle 267, a distal end section 269 and a bushing 271. The slideable needle 262 consists of a shaft 264, a needle stop 266, a metal needle 268 and a finger push button 270.

The patient would receive an injection port assembly with the plastic needle 267 placed into the septum of the main body of the injection port and with the distal end section 269 in contact with the top of the main body. The spring 263 normally urges the slidable needle 262 to be in the position shown in Figure 18. The patient would then hold the body 265 between his thumb and middle finger and use his index finger to apply a force to the finger push button 270 thus causing the slidable needle 262 to assume the position shown in Figure 19. In that position, the needle 268 (which would be located within a flexible cannula) would be used to place the distal end of the flexible cannula through the skin and into the subcutaneous fat. The injection port assembly would then adhere to the skin, the needle assembly 260 would be pulled out, and the slidable needle 262 would.automatically be placed into the position shown in Figure 18. Thus, the sharpened point of the needle 268 would be shielded by the housing 261 thereby precluding inadvertent needle sticks. The needle assembly 260 would then be disposed on in the safe, needle retracted position shown in Figure 18.

It is envisioned that a variety of other designs for safety needles could be used for placement of injection ports; the common feature being that the sharpened needle point is retracted into a plastic needle housing.

As will be apparent, various modifications, adaptations, and alternative designs will be possible in light of the above teachings and without departing from the scope of the invention herein described and hereinafter claimed.

Claims

1. A subcutaneous injection system for the periodic or long term delivery of a medicament subcutaneously to a patient, said system comprising:

   a generally flat, moulded plastics body portion (11,111) having a generally planar undersurface (20) which is shaped to engage against the surface of the skin in surrounding relationship to the site of delivery of the medicament to the patient;

   a flexible cannula (14) projecting downwardly from the underside of the moulded body portion, said cannula having a central lumen which communicates with a passageway (13A) formed in said body for the throughflow of medicament from an inlet port in the moulded body to

the cannula, and through the lumen of the cannula to a delivery port (18) formed in the distal end of the cannula; and

a stylet needle (8) removably insertable into the cannula (14) through the moulded body (11), said needle having a length greater than that of the cannula so that, when inserted therein, the tip of the needle projects beyond the distal end of the cannula,

said needle having adjacent its tip an outwardly projecting shoulder which, when the needle is inserted into the flexible cannula, engages against an inwardly projecting shoulder formed in the lumen of the cannula adjacent its distal end, so that engagement of the needle into the cannula serves to tension the flexible cannula and prevent the cannula from buckling as the needle and cannula are pushed through the patient's skin, the needle thereafter being withdrawn to leave the cannula in place and with the undersurface of the moulded body portion lying against the patient's skin.

2. A subcutaneous delivery system according to claim 1, wherein the stylet needle (8) is introduceable into the flexible cannula (14) through a self-sealing septum (22) located in a cavity formed in the moulded body portion (11).

3. A subcutaneous delivery system according to claim 1 or 2, wherein the undersurface of the body portion is coated with a layer of adhesive which, when the delivery system is in place, adhesively bonds the moulded body portion (11) to the patient's skin.

4. A subcutaneous delivery system according to any one of claims 1 to 3, wherein the moulded body portion is provided with a quick release connector by means of which the system can be rapidly connected to, or disconnected from, an external supply of the said medicament.

5. A subcutaneous delivery system according to claim 4, wherein the quick release connector is provided on the body portion itself, or at the end of short length of tubing and at a distance of no more than 25 cms from the main body portion, preferably from 5 to 10 cms.

6. A subcutaneous delivery system according to any one of claims 1 to 5, comprising a removable needle guard detachably mounted on the underside of the moulded body in surrounding relationship to the flexible cannula to shield and protect the needle, and the flexible cannula, prior to use.

7. A subcutaneous delivery system according to claim 6, wherein the needle guard comprises a tubular shield with a closed distal end which completely encloses the needle and the flexible cannula prior to use.

8. A subcutaneous delivery system according to claim 7, wherein the tubular shield contains a quantity of antibiotic ointment thereby to provide tip of the needle and the distal end of the flexible cannula with an antibiotic coating prior to puncturing of the patient's skin by the needle and placement of the cannula into the subcutaneous tissue.

9. A subcutaneous delivery system according to any one of claims 1 to 8, wherein the delivery port in the flexible cannula is a side delivery port.

10. A subcutaneous delivery system according to any one of claims 1 to 9, which comprises an in-line bacterial filter to filter the medicament prior to the delivery thereof to the patient through the delivery port in the flexible cannula.

11. A subcutaneous delivery system according to any one of claims 1 to 10, wherein the needle has a central lumen extending partially along the length of the needle from the proximal end thereof, said lumen having a side entry port intermediate the ends of the needle, which side entry port intersects the flow passageway in the moulded body portion, when the needle is inserted therethrough into the flexible cannula thereby to permit air to be flushed from the passageways in the body portion prior to retraction of the needle and feeding of the medicament to the cannula through those passageways.

12. A subcutaneous delivery system according to any one of claims 1 to 11, wherein the stylet needle (268) is retractably mounted in a housing (261) from which it may be axially advanced against a spring bias to an extended position passing through the moulded body portion and into the flexible cannula, and into which it is retracted by said spring bias, upon withdrawal of the needle and after the placement of the flexible cannula into the subcutaneous tissue of the patient.

13. A subcutaneous delivery system according to any one of claims 1 to 12, wherein the peripheral region, at least of the moulded body portion is flexible to permit that region at least to adapt to the contour of the skin when in place thereon, and to flex with the skin.

14. A subcutaneous delivery system according to any one of claims 1 to 13, wherein the main body por-

tion is a one-piece plastics moulding.

15. A subcutaneous delivery system according to any one of claims 1 to 14, wherein the length of the flexible cannula is from 0.2 to 0.8 cms.

16. A device for delivery of medication from an external source through a patient's skin comprising:

a needle assembly consisting of a needle having proximal and distal sections and a handle fixedly attached onto the needle's proximal section, the proximal section of the needle being a hollow tube with a side entry port and the needle having an exit port at the needle's proximal end; and

an injection port assembly consisting of a main body having an entry lumen which has a distal end and an exit lumen, the side entry port of the needle being joined to and in fluid communication with the distal end of the entry lumen thus allowing medication to flow through the needle's side entry port so that the device can be primed through the needle either prior to or after insertion of the needle through the patient's skin.

17. A device for delivery of medication from an external source through a patient's skin comprising:

a needle assembly consisting of a needle having proximal and distal sections and a handle fixedly attached onto the needle's proximal section;

a needle guard that is placed over the distal section of the needle, the needle guard being adapted for removal prior to insertion of the needle through the patient's skin; and, an injection port assembly consisting of a main body having a bottom surface and a top surface and having an entry lumen and an exit lumen which lumens are in fluid communication with each other after the needle assembly is withdrawn out of the main body, the exit lumen being formed within a flexible cannula that protrudes in a generally downward direction from the bottom surface of the main body, the bottom surface also having a groove at least partially surrounding the cannula into which groove the needle guard is removably inserted.

18. A device for delivery of medication from an external source through a patient;s skin comprising:

a needle assembly consisting of a needle having proximal and distal sections and a handle fixedly attached onto the needle's proximal section;

an injection port assembly consisting of a main body having a bottom surface and a top surface and an entry lumen and an exit lumen which lumens are in fluid communication with each other after the needle assembly is withdrawn from the main body, the exit lumen being formed within a flexible cannula that protrudes in a generally downward direction from the bottom surface of the main body;

a needle guard having a proximal portion and a distal portion and a proximal end that is removably attached to the main body, the needle guard being adapted to cover the needle's distal section prior to insertion of the needle through the patient's skin, the needle guard having a closed distal end forming an enclosed chamber within the needle guard when the needle guard is attached to the main body, the needle guard also having an antibiotic ointment placed within the enclosed chamber.

19. A device for delivery of medication from an external source through a patient's skin comprising:

a needle assembly consisting of a needle having proximal and distal sections and a handle fixedly attached onto the needle's proximal section; and

an injection port assembly consisting of a main body having a bottom surface and a top surface and an outer perimeter situated at the intersection of the top and bottom surfaces, the main body also having an entry lumen and an exit lumen which lumens are in fluid communication with each other after the needle assembly is withdrawn from the main body, the exit lumen being formed within a flexible cannula that protrudes in a generally downward direction from the main body, the entry lumen being joined to a tubular body extension extending in the proximal direction generally parallel to the patient's skin, the tubular body extension having a quick-release connector at its proximal end, which connector is located at a distance from the outer perimeter of the main body which is less than the diameter of the main body.

20. A device for delivery of medication from an external source through a patient's skin comprising:

a needle assembly consisting of a needle having proximal and distal sections and a handle fixedly attached onto the needle;s proximal section; and

an injection port assembly consisting of a main body having an entry lumen which has a distal end and an exit lumen which has a proximal end, the exit lumen being formed within a flexible cannula that protrudes in a generally downward direction from the main body, the injection port assembly also including a self-sealing septum through which the needle is placed, the septum having a bottom surface which is situated at the luminal intersection so that when the needle is re-

moved from the septum, the entry and exit lumens are joined and in fluid communication with each other so as to provide a continuous flow path through the luminal intersection.

21. A device for delivery of medication from an external source through a patient's skin comprising:

a needle assembly consisting of a needle having proximal and distal sections and a handle fixedly attached onto the needle's proximal section; and,

an injection port assembly consisting of a main body having an exit lumen which has a proximal end, the exit lumen being formed within a flexible cannula that protrudes in a generally downward direction from the main body, the injection port assembly also including a bacterial filter and a single septum, the septum and the main body forming an injection chamber therebetween, the injection chamber being separated from the proximal end of the exit lumen by means of the bacterial filter, the single septum being adapted to first allow penetration by the needle of the needle assembly and then being further adapted to allow penetration by a hypodermic syringe injection needle after the needle assembly is removed from the septum, the septum having an outer surface that has an indication means to indicate correct placement of the hypodermic syringe injection needle so that medication injected from the syringe enters the injection chamber before passing through the bacterial filter into the exit lumen.

22. An injection port for delivery of medication from an external source through a patient's skin comprising:

a generally flat, disk shaped main body formed from a single moulded elastomer including a septum formed integral at the centre of the main body; and,

a cannula section formed from a single moulded elastomer of a harder durometer as compared to the elastomer of the main body, the cannula section being joined with a pressure tight seal to the main body, the cannula section further having a flexible elongated cannula that protrudes in a generally downward direction from the main body.

23. A device for delivery of medication from an external source through a patient's skin comprising:

an injection port assembly having top and bottom surfaces and consisting of a main body, a cannula section and an adhesive section, the cannula section having an elongated cannula with a central lumen that protrudes in a generally downward direction from the injection port assembly, the lumen having proximal and distal ends, the lumen's proximal end being situated just below a septum that is formed integral with and at the centre of the main body, the cannula section further including two holes each including an engaging means for attachment to a fluid connector engaging means.

24. A device for delivery of medication from an external source through a patient's skin comprising:

an injection port assembly having top and bottom surfaces and consisting of a main body, a cannula section and an adhesive section, the cannula section having an elongated cannula with a central lumen that protrudes in a generally downward direction from the injection port assembly; and,

a needle assembly including a housing and a slidable metal needle that can be advanced into and through the cannula for subcutaneous insertion of the cannula, the slidable metal needle having a sharpened needle point at its distal end that is adapted to be withdrawn into the housing so that the sharpened needle point is completely shielded by the housing.

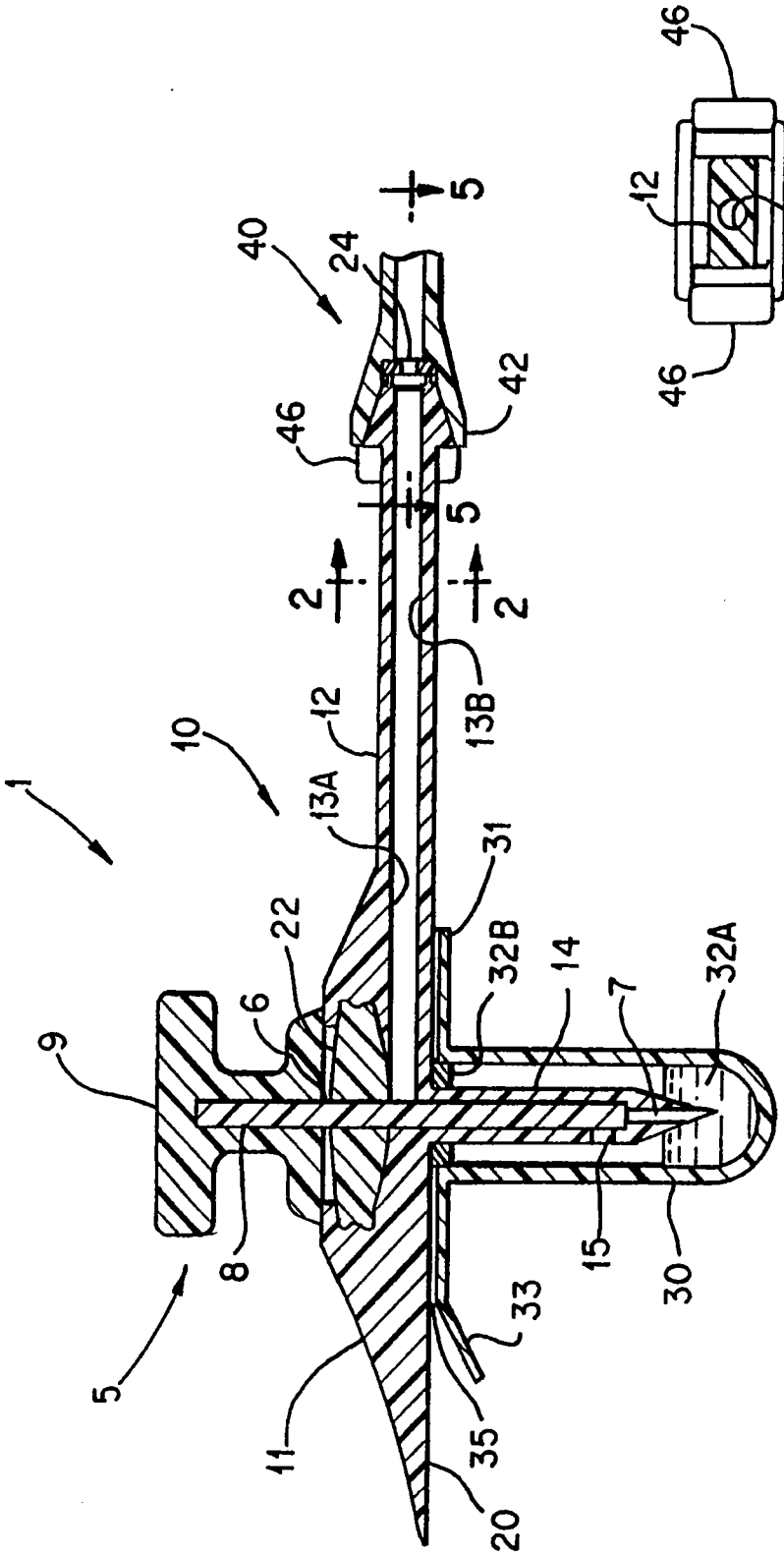
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FIG. 1

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FIG. 2

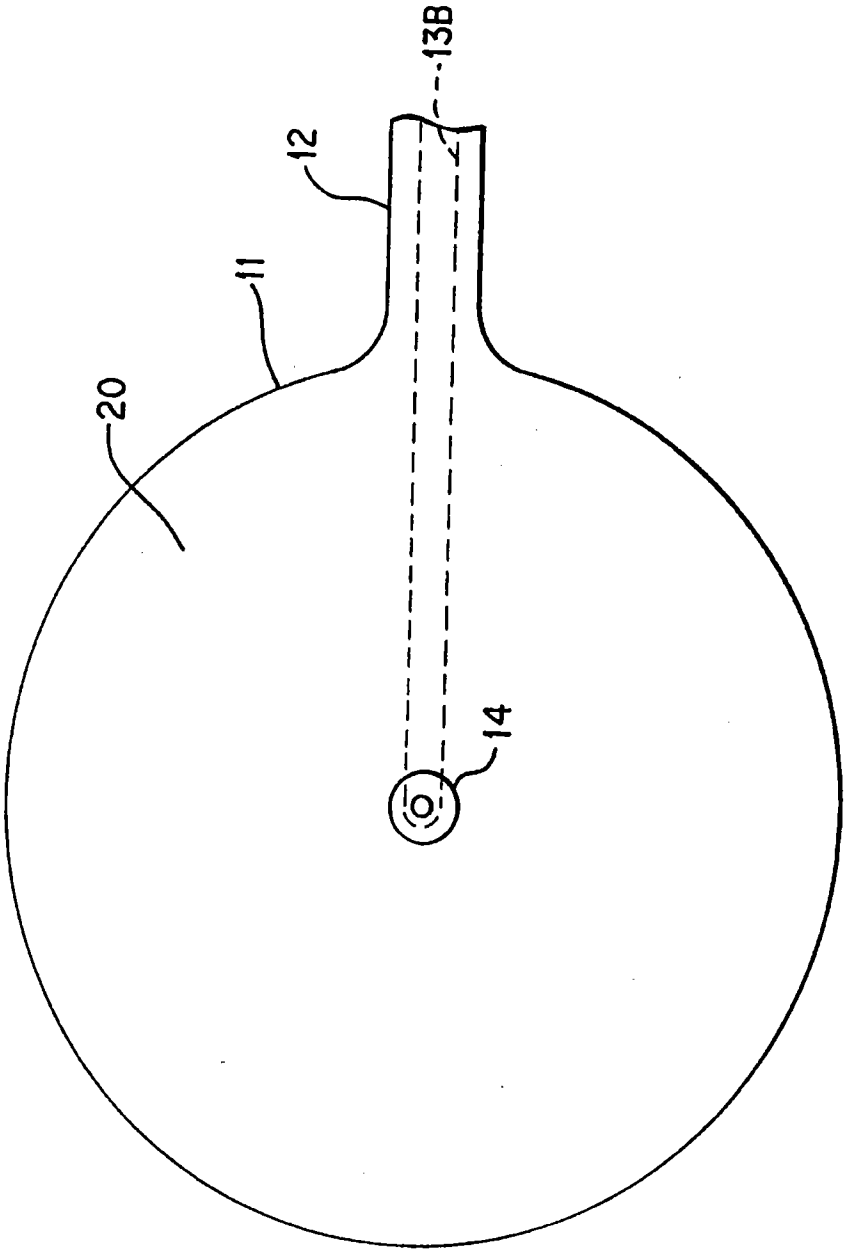

FIG.3

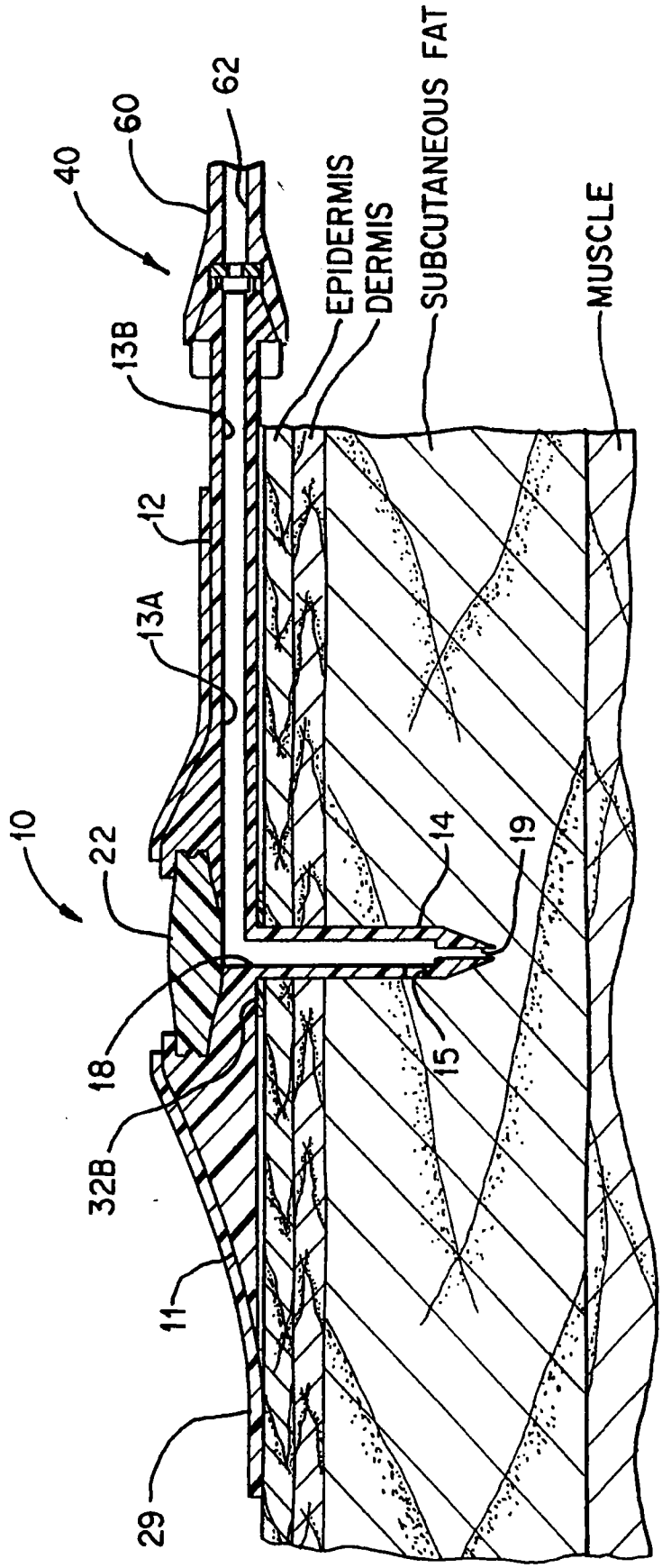
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FIG. 4

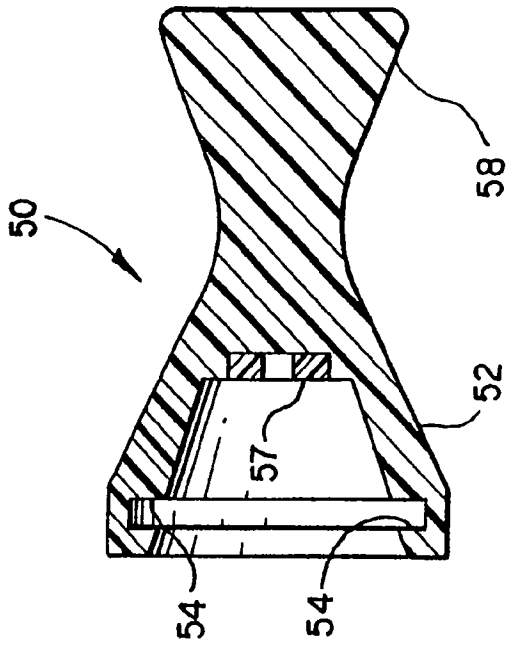

FIG. 6

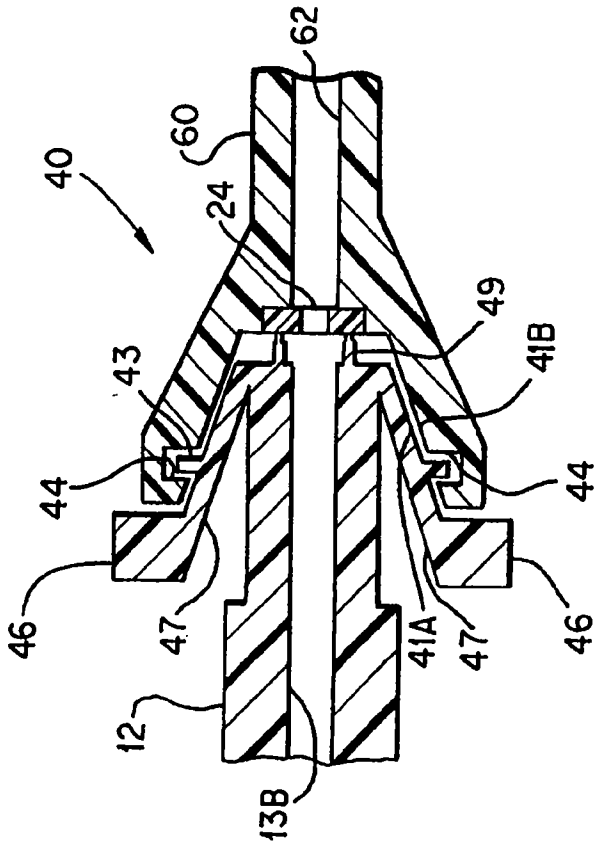

FIG. 5

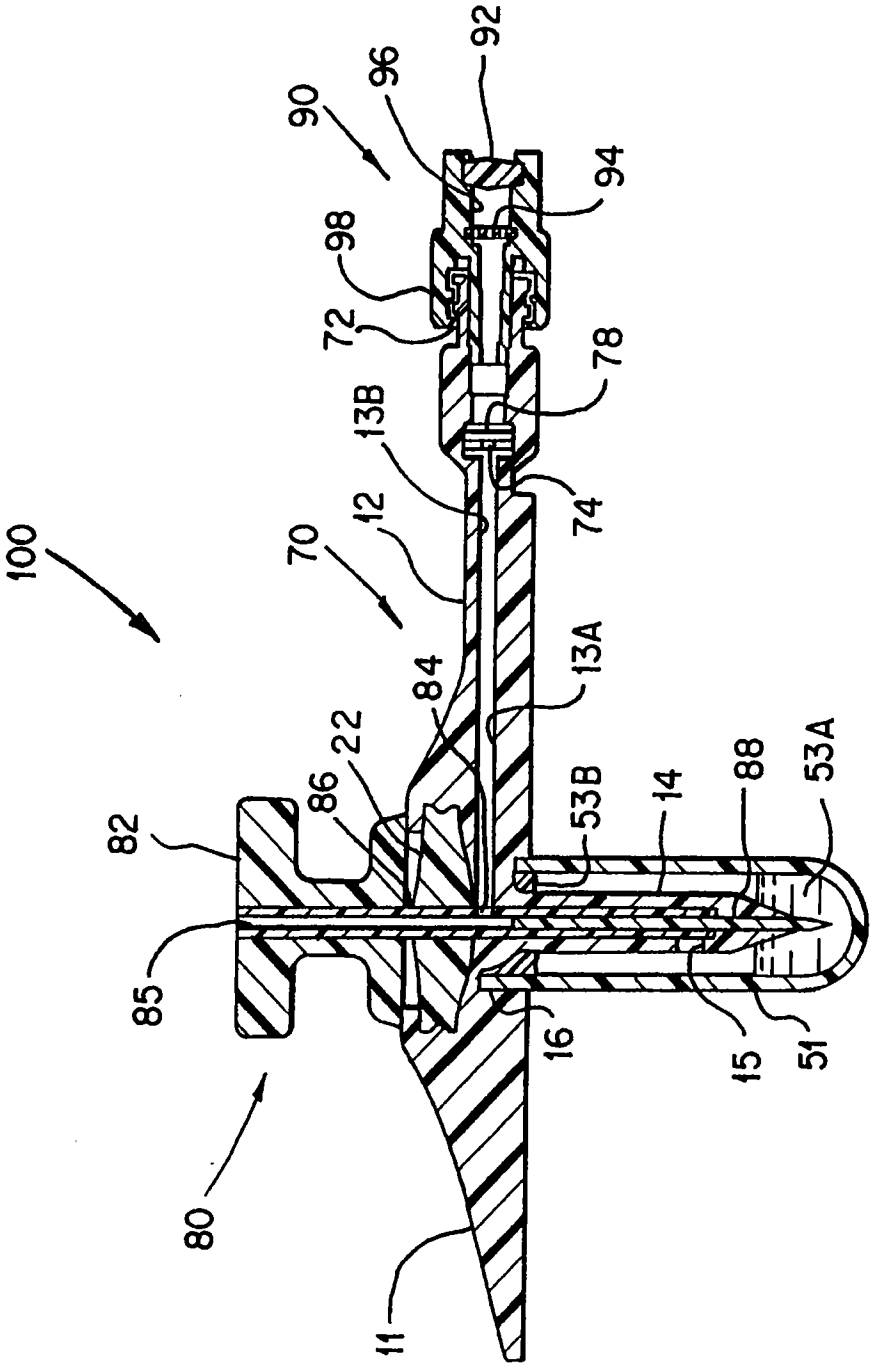
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FIG. 7

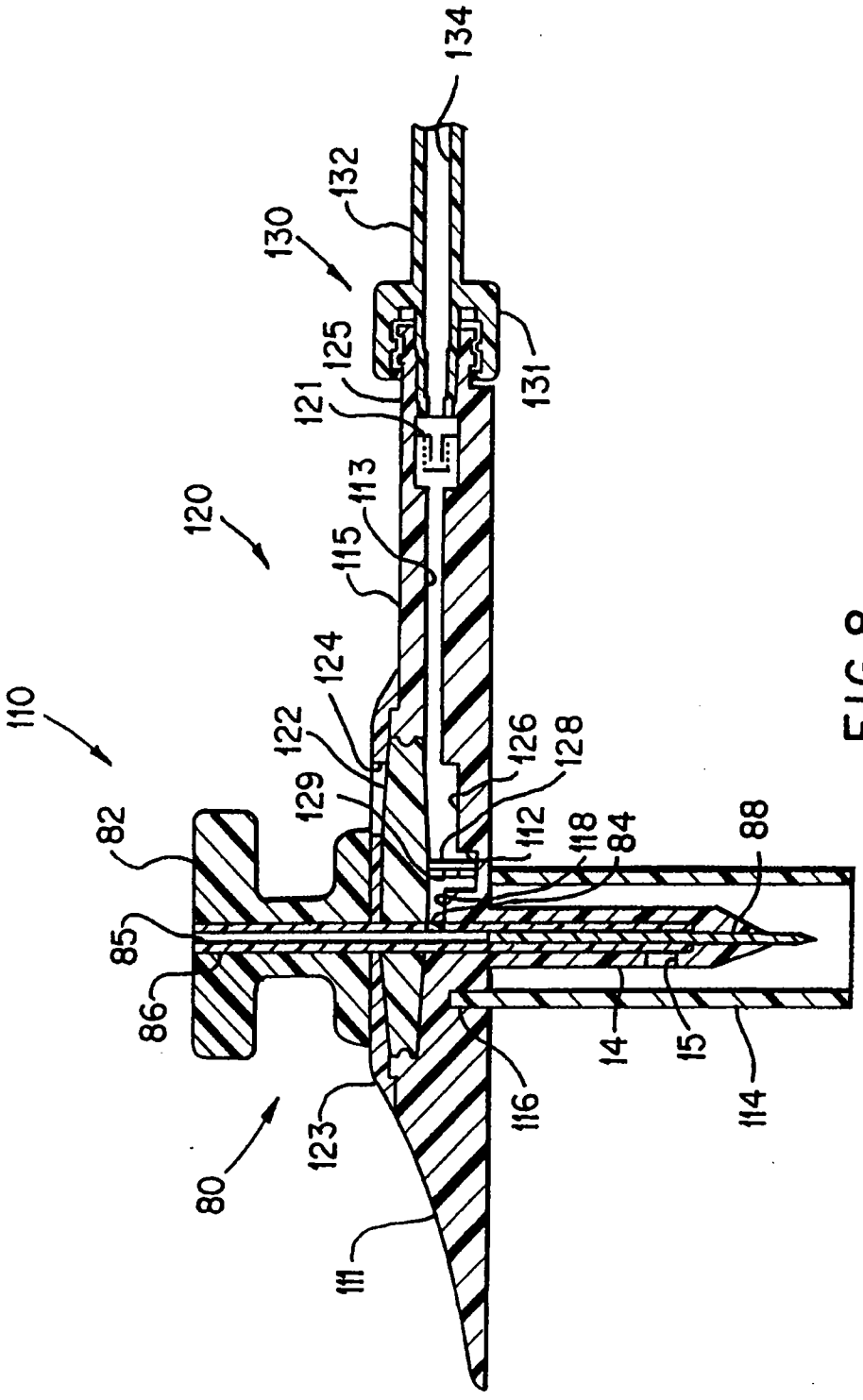
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FIG.8

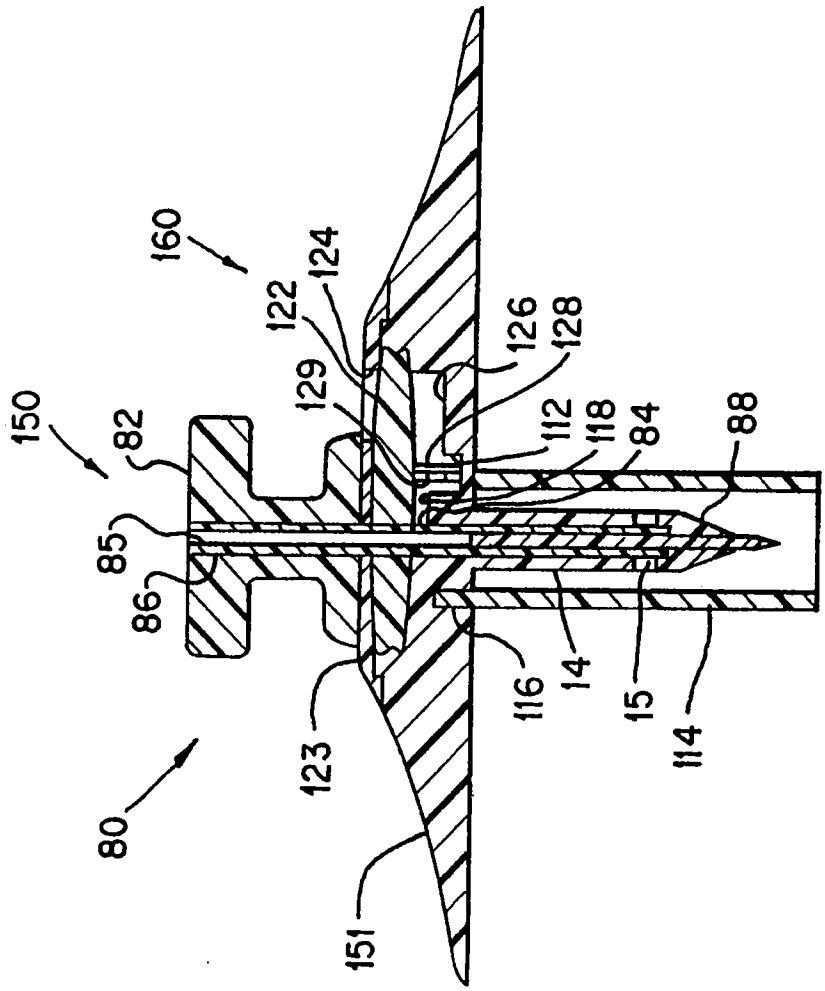
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FIG. 9

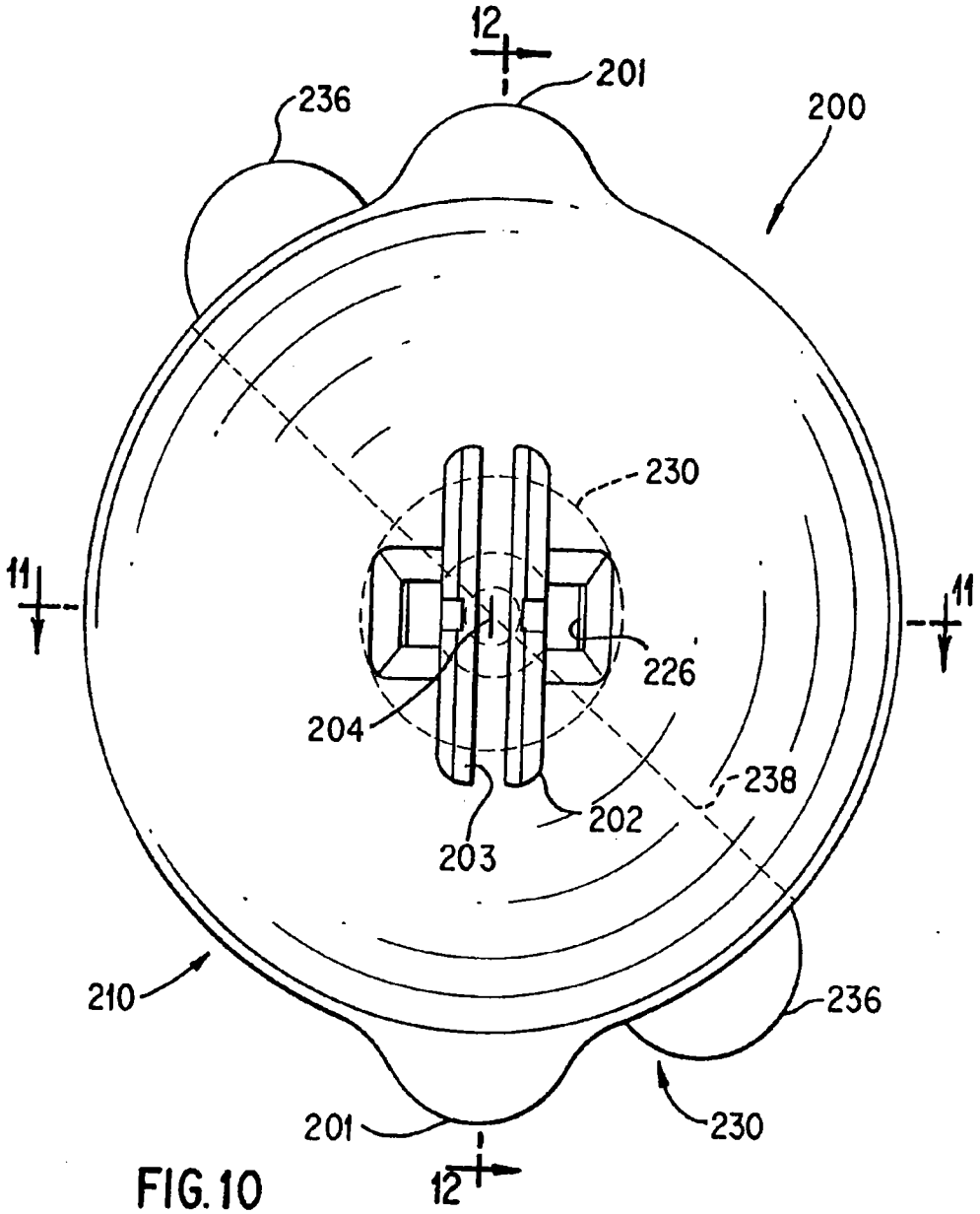
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FIG. 10

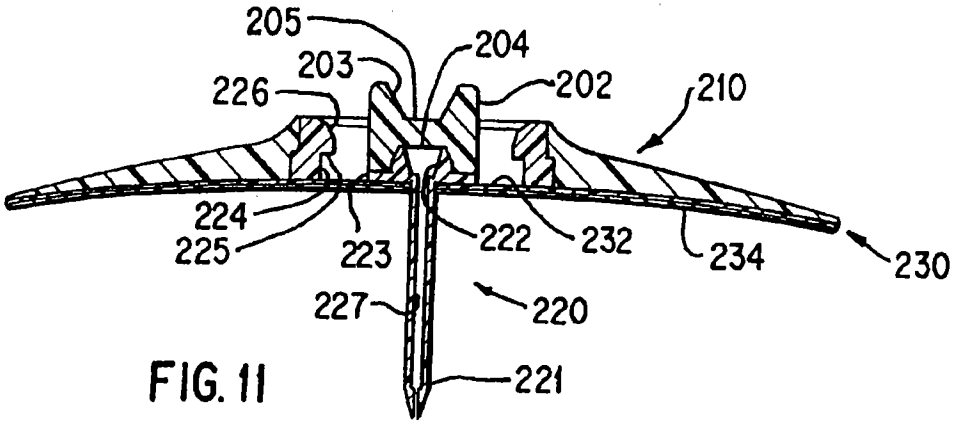
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FIG. 11

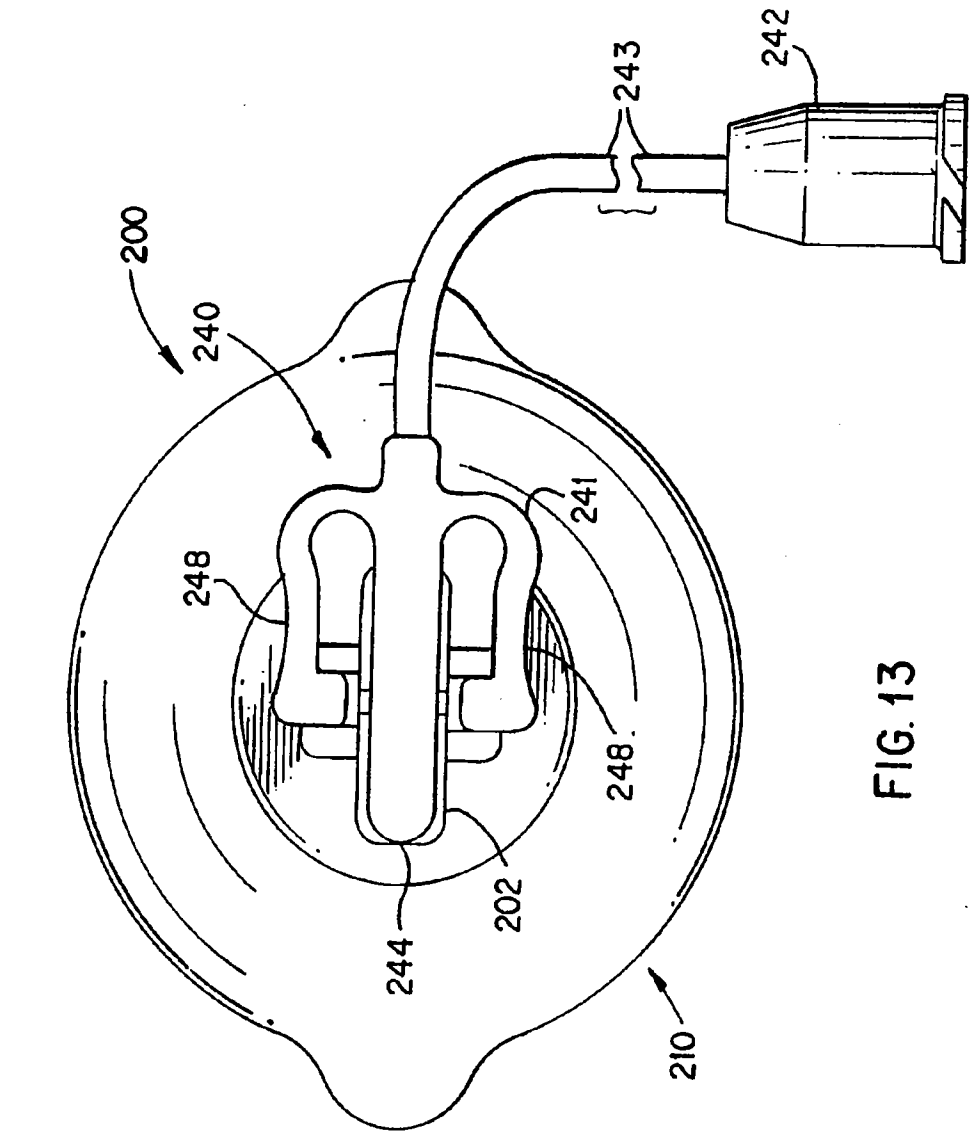
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FIG. 13

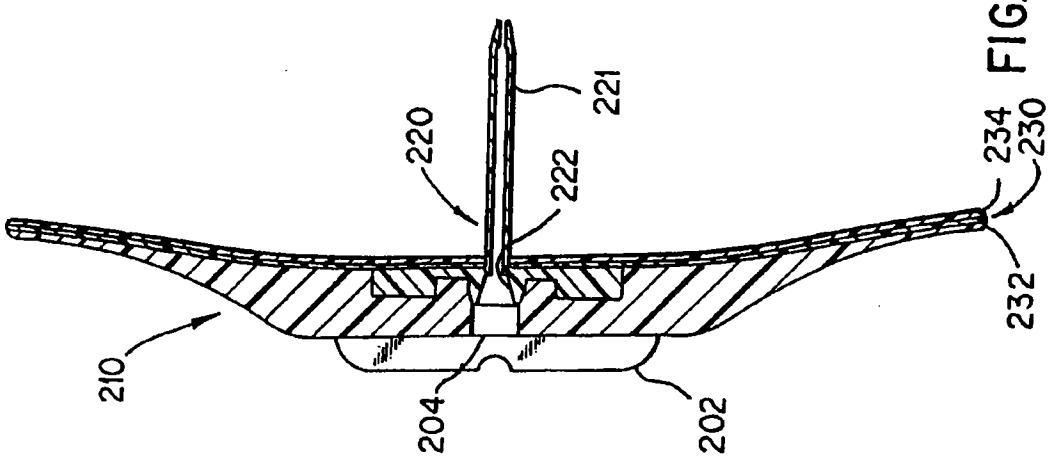
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FIG. 12

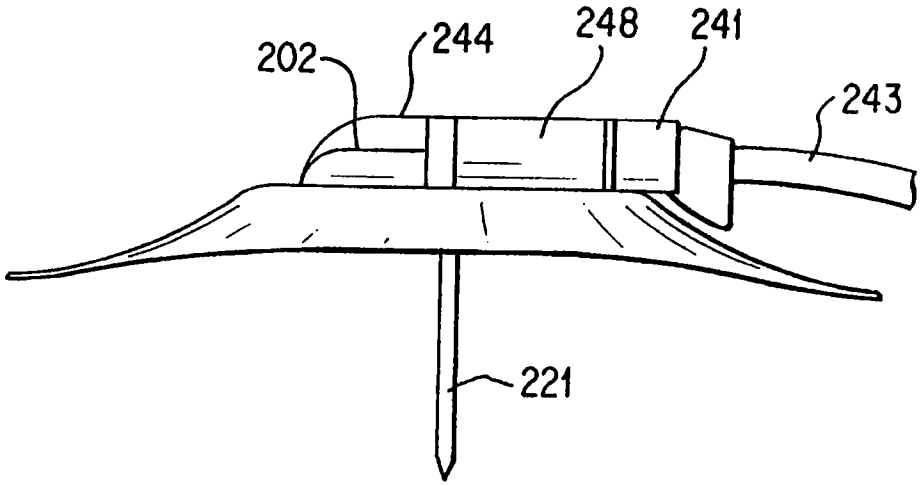

FIG. 14

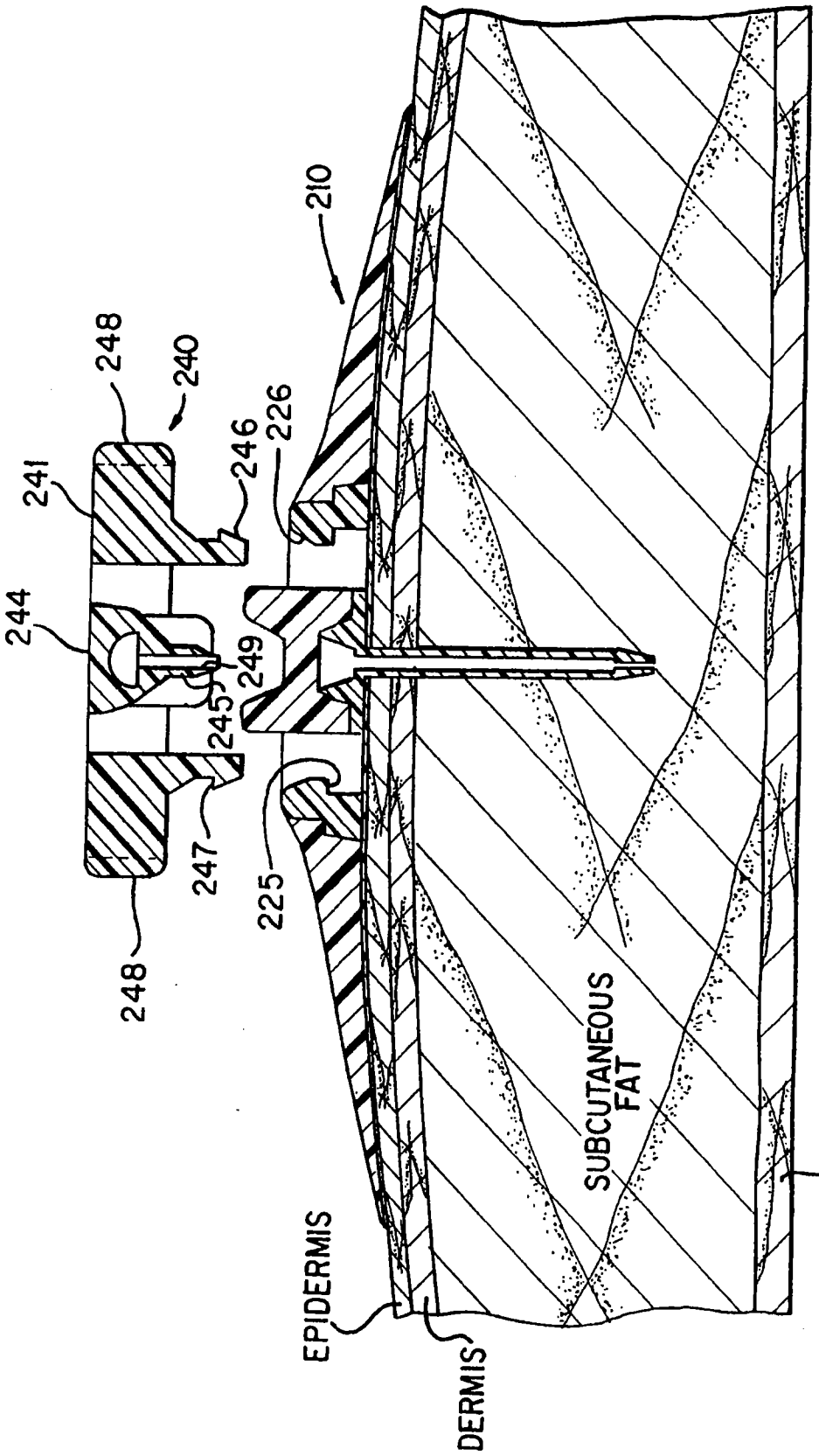
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FIG. 15

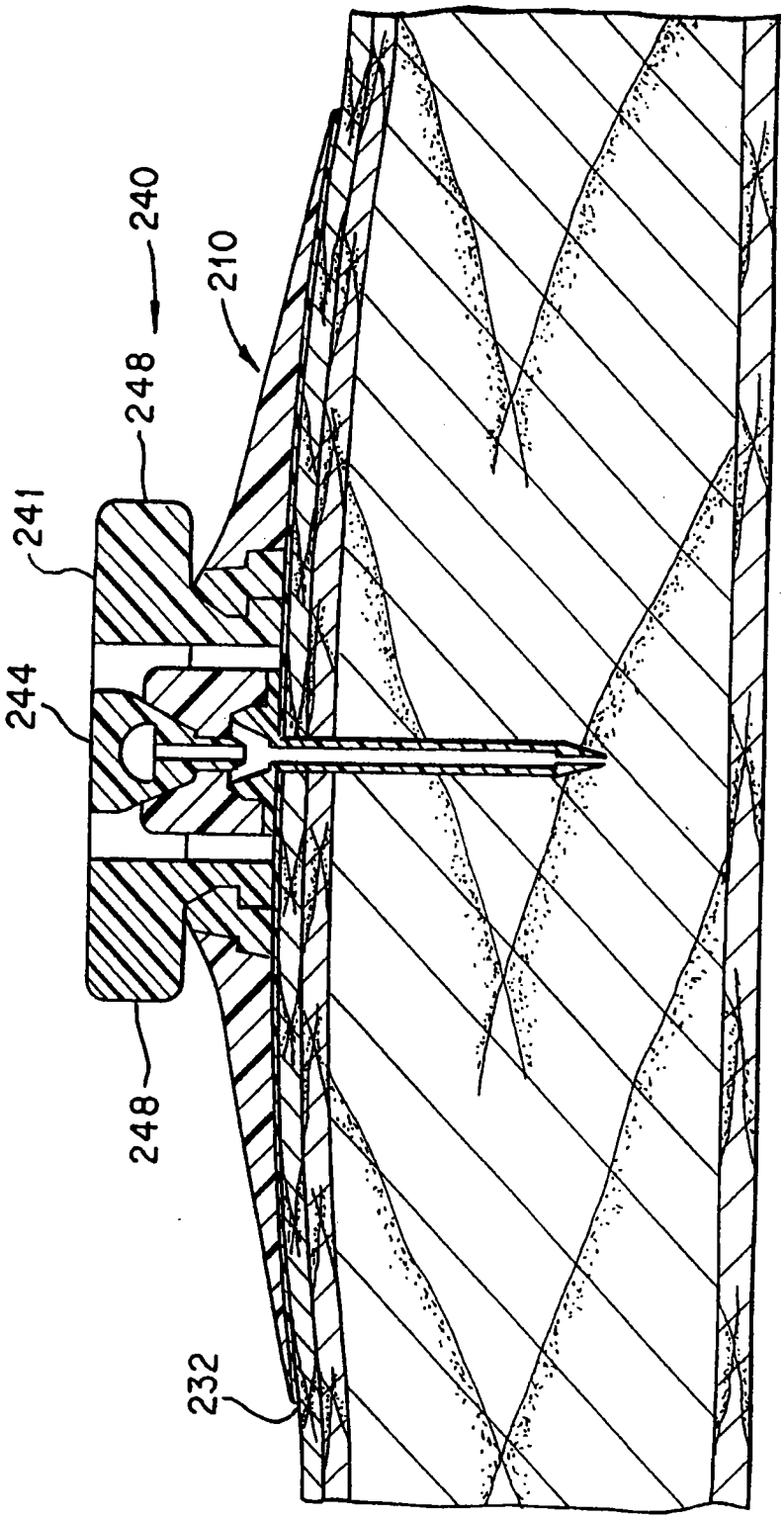

FIG. 16

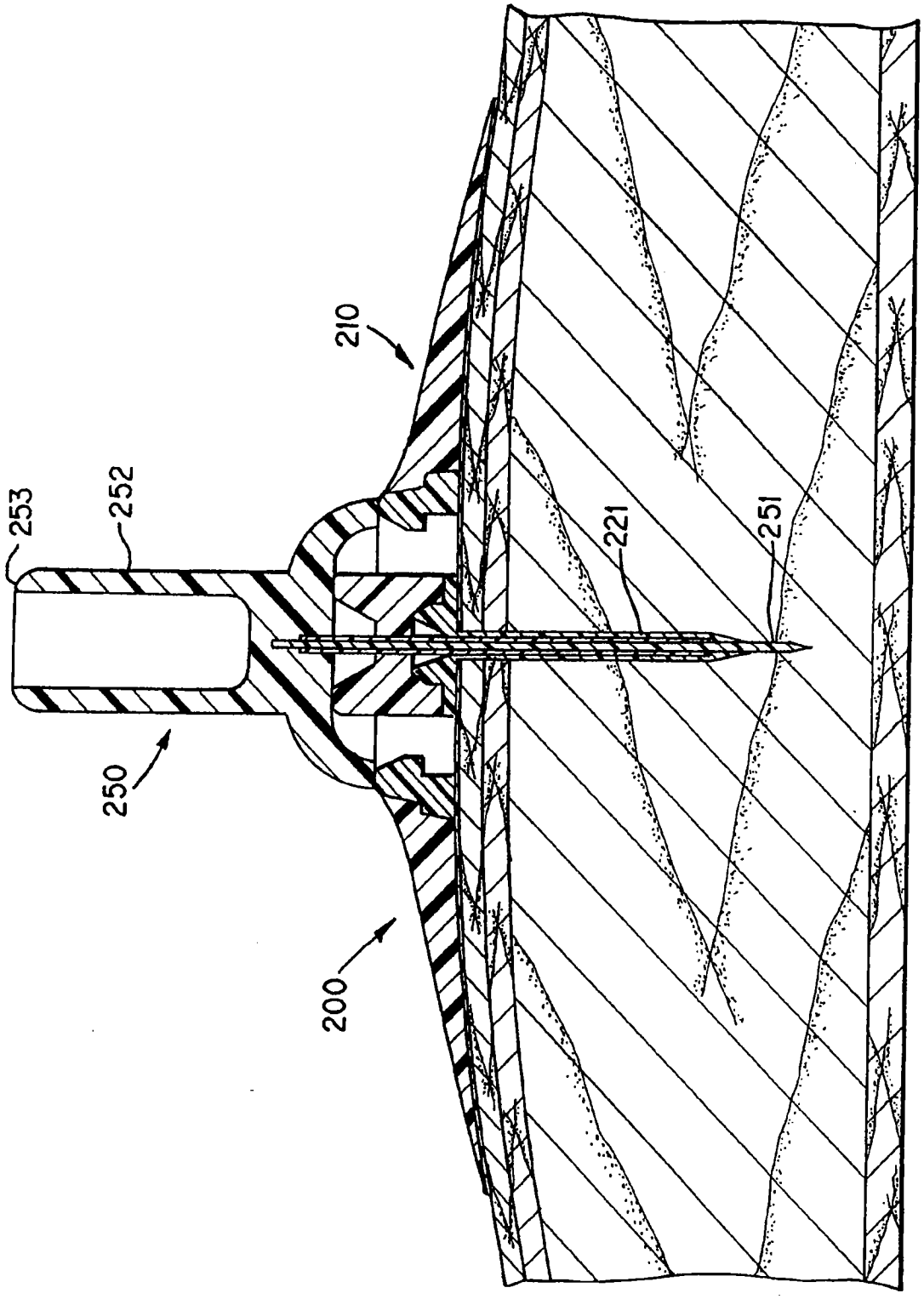

FIG.17

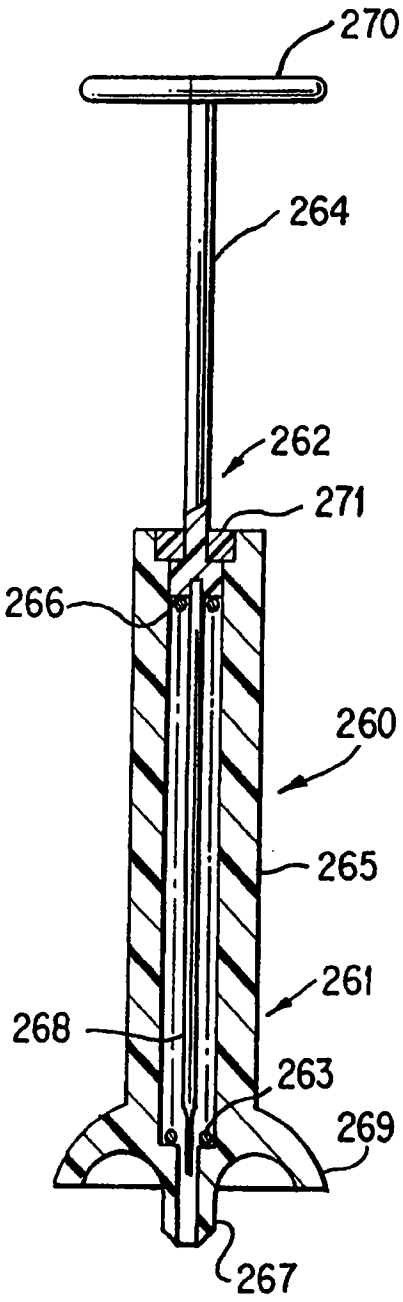
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FIG. 18

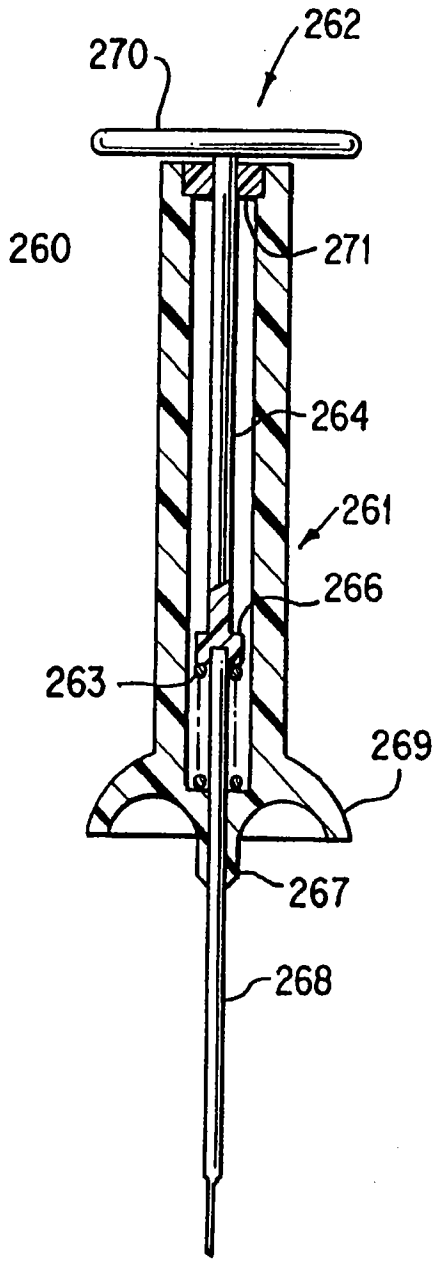
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FIG. 19